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PREFACE

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ABOUT AUTOMATED EXTERNAL DEFIBRILLATION

The following considerations and guidelines apply when using the LIFEPAK® 20 defibrillator/monitor as an automated external defibrillator (AED).

Operator Considerations

The LIFEPAK 20 defibrillator/monitor, when in AED mode, is a semiautomatic defibrillator that uses a patented Shock Advisory System™. This software algorithm analyzes the patient's electrocardiographic (ECG) rhythm and indicates whether or not it detects a shockable rhythm. The LIFEPAK 20 defibrillator/monitor in AED mode requires operator interaction to defibrillate the patient.

The LIFEPAK 20 defibrillator/monitor in AED mode is intended for use by personnel who are authorized by a physician/medical director and have, at a minimum, the following skills and training:

- CPR training.
- AED training equivalent to that recommended by the American Heart Association.
- Training in the use of the LIFEPAK 20 defibrillator/monitor in AED mode.

Indications

The AED mode is to be used only on patients in cardiopulmonary arrest. The patient must be unconscious, pulseless, and not breathing spontaneously before using the defibrillator to analyze the patient's ECG rhythm.

Contraindications

In AED mode, the LIFEPAK 20 defibrillator/monitor is contraindicated for use on pediatric patients less than eight years old.

In AED mode, the LIFEPAK 20 defibrillator/monitor is not to be used on patients who are breathing, have a pulse, and/or are conscious.

ABOUT DEFIBRILLATION THERAPY

Indications

Defibrillation is a recognized means of terminating certain potentially fatal arrhythmias, such as ventricular fibrillation and symptomatic ventricular tachycardia.

The biphasic defibrillation waveform used in this device has only been clinically tested on adults; it has not been tested on pediatric patients.

A direct current defibrillator applies a brief, intense pulse of electricity to the heart muscle. The LIFEPAK 20 defibrillator/monitor delivers this energy through disposable electrodes, standard paddles or internal paddles applied to the patient's chest. Delivery of this energy in the synchronized mode is a method for treating atrial fibrillation, atrial flutter, paroxysmal supraventricular tachycardia, and, in relatively stable patients, ventricular tachycardia.

Defibrillation is only one aspect of the medical care required to resuscitate a patient with a shockable ECG rhythm. Depending on the situation, other supportive measures may include:

Cardiopulmonary resuscitation (CPR)

Administration of supplemental oxygen

Drug therapy

Successful resuscitation is related to the length of time between the onset of a heart rhythm that does not circulate blood (ventricular fibrillation, pulseless ventricular tachycardia) and defibrillation. The American Heart Association has identified the following as critical links in the chain of survival from cardiac arrest:

- Early access
- Early CPR by first responders or bystanders
- Early defibrillation
- Early advanced life support

The physiological state of the patient may affect the likelihood of successful defibrillation. Thus, failure to resuscitate a patient is not a reliable indicator of defibrillator performance. Patients will often exhibit a muscular response (such as jumping or twitching) during an energy transfer. The absence of such a response is not a reliable indicator of actual energy delivery or device performance. For further information, refer to the booklet, *Defibrillation: What You Should Know.*

Contraindications

Defibrillation is contraindicated in the treatment of Pulseless Electrical Activity (PEA) such as idioventricular or ventricular escape rhythms, and in the treatment of asystole.

ABOUT NONINVASIVE PACING

Indications

A noninvasive pacemaker is a device that delivers an electrical stimulus to the heart, causing cardiac depolarization and myocardial contraction. The energy is delivered through large adhesive electrodes placed on the chest. Noninvasive pacing as a therapy is indicated for patients with symptomatic bradycardia or asystole. In addition to noninvasive pacing, other supportive measures may be necessary.

Among other factors, it is recognized that successful pacing of a patient is related to the length of time between the onset of a dysrhythmia and the initiation of pacing. Rapid pacing and prompt follow-up care are essential. The physiologic state of the patient may affect the likelihood of successful pacing or of skeletal muscle activity. The failure to successfully pace a patient is not a reliable indicator of pacemaker performance. Similarly, the patient's muscular response to pacing is not a reliable indicator of energy delivered. Refer to the booklet, *Noninvasive Pacing: What You Should Know* for further information.

Contraindications

Noninvasive pacing is contraindicated for the treatment of ventricular fibrillation. Severe hypothermia is a relative contraindication to pacing a patient with bradycardia.

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ABOUT SPO2 MONITORING

Indications

A pulse oximeter is a noninvasive device that checks the saturation of oxygen in arterial blood (SpO2). It is indicated for use in any patient who is at risk of developing hypoxemia. The pulse oximeter uses an optical sensor that directs light through the patient's finger and then measures the received light with a detector. This received light is translated into a saturation percentage and is displayed as an SpO2 reading.

Contraindications

None known.

SAFETY INFORMATION

This section provides important information to help you operate the LIFEPAK 20 defibrillator/monitor. Familiarize yourself with all of these terms, warnings, and symbols.

Terms	page 1-2
General Warnings and Cautions	1-2
Symbols	1-3

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TERMS

The following terms are used either in these Operating Instructions or on the LIFEPAK 20 defibrillator/monitor:

Danger: Immediate hazards that will result in serious personal injury or death.
Warning: Hazards or unsafe practices that may result in serious personal injury or death.
Caution: Hazards or unsafe practices that may result in minor personal injury, product damage, or property damage.

GENERAL WARNINGS AND CAUTIONS

The following are general warning and caution statements. Other specific warnings and cautions are provided as needed in other sections of these operating instructions.

WARNINGS!

Shock hazard.

The defibrillator delivers up to 360 J of electrical energy. Unless properly used as described in these Operating Instructions, this electrical energy may cause serious injury or death. Do not attempt to operate this device unless thoroughly familiar with these operating instructions and the function of all controls, indicators, connectors, and accessories.

Shock hazard.

Do not disassemble the defibrillator. It contains no operator serviceable components and dangerous high voltages may be present. Contact authorized service personnel for repair.

Shock or fire hazard.

Do not immerse any portion of this device in water or other fluids. Avoid spilling any fluids on device or accessories. Do not clean with ketones or other flammable agents. Do not autoclave or sterilize this device or accessories unless otherwise specified.

Possible fire or explosion.

Do not use this device in the presence of flammable gases or anesthetics. Use care when operating this device close to oxygen sources (such as bag-valve-mask devices or ventilator tubing). Turn off gas source or move source away from patient during defibrillation.

Possible electrical interference with device performance.

Equipment operating in close proximity may emit strong electromagnetic or radio frequency interference (RFI), which may affect the performance of this device. RFI may result in distorted ECG, failure to detect a shockable rhythm, or cessation of pacing. Avoid operating device near cauterizers, diathermy equipment, or cellular phones. Maintain equipment separation of at least 1.2 m (4 ft) and do not rapidly key EMS radios on and off. Contact Medtronic technical support if assistance is required.

Possible electrical interference.

This defibrillator may cause electromagnetic interference (EMI) especially during charge and energy transfers. EMI may affect the performance of equipment operating in close proximity. Verify the effects of defibrillator discharge on other equipment prior to using defibrillator in an emergency situation, if possible.

Possible defibrillator shutdown.

When operating on battery power, the large current draw required for defibrillator changing may cause the defibrillator to reach shutdown voltage levels with no low battery warning. If the defibrillator shuts down without warning, or if a *LOW BATTERY. CONNECT TO AC POWER* message appears on the monitor screen, immediately connect the ac power cord to an outlet.

WARNINGS!

Possible improper device performance.

Using other manufacturers' cables, electrodes, or batteries may cause the device to perform improperly and invalidates the safety agency certification. Use only the accessories specified in these Operating Instructions.

Possible failure to detect an out of range condition.

Reselecting QUICK SET will reset the alarm limits around the patient's current vital sign values. This may be outside the safe range for the patient.

Safety risk and possible equipment damage.

Monitors, defibrillators, and their accessories (including electrodes and cables) contain ferromagnetic materials. As with all ferromagnetic equipment, these products must not be used in the presence of the high magnetic field created by a Magnetic Resonance Imaging (MRI) device. The high magnetic field created by an MRI device will attract the equipment with a force sufficient to cause death or serious personal injury to persons between the equipment and the MRI device. This magnetic attraction may also damage the equipment. Skin burns will also occur due to heating of electrically conductive materials such as patient leads and pulse oximeter sensors. Consult the MRI manufacturer for more information.

Note: Medtronic devices, electrodes, and cables are latex-free.

SYMBOLS

The symbols below may be found in these operating instructions or on various configurations of LIFEPAK 20 defibrillator/monitor and accessories:

Defibrillation-proof type CF terminal

Defibrillation protected, type BF patient connection

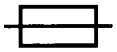
Attention, consult accompanying documents

Warning, high voltage

Type BF patient connection

Static sensitive device (SSD)

Safety ground. Protective earth connection


Fuse

Equipotential connector

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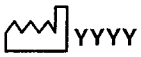
+	Positive terminal
—	Negative terminal
LOT YYWW	Lot number (batch code)
	Use by date shown: yyyy-mm-dd
REF	Reorder number
	Date of manufacture
	Single use only
	Indoor use only
	Alarm on
	Alarm off
	VF/VT alarm on
	VF/VT alarm silenced
>	Greater than
<	Less than
J	Joules
	Contrast
	Adult defibrillation paddle
	Infant defibrillation paddle
	Home screen button

Heart rate/pulse rate indicator

Shock count (x) on screen

Mark of conformity according to the European Medical Device Directive 93/42/EEC.

Canadian Standards Association certification for Canada and the United States.

Recognized component mark for Canada and the United States

DC voltage

AC voltage

On (power: connection to the ac mains)

Off (power: disconnection from the ac mains)

Power on/off

[signal] Input

[signal] Output

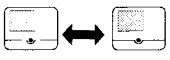
This end up

Fragile/breakable
Handle with care

Protect from water

Recycle this item

System connector/Data in



LIFEPAK 20 defibrillator/monitor to LIFEPAK 20 defibrillator/monitor cable (See Send Configuration Setup Menu, page 8-10)

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Turn counterclockwise to unlock

Switch on

Switch off

Pace arrow, noninvasive pacing

Pace arrow, internal pacing

R-wave sense marker

Event marker

Biphasic defibrillation shock

Shock button

!USA — For USA audiences only

CAT — Twelve-digit catalog number that identifies the item

MIN — Manufacturer's Item Number

Rx Only — Federal law restricts this device to sale by or on the order of a physician

BASIC ORIENTATION

This section provides a basic orientation to the LIFEPAK 20 defibrillator/monitor.

Introduction	page 2-2
Unpacking and Inspecting	2-2
Controls, Indicators, and Connectors	2-2
Entering Patient Data	2-14
Setting Alarms	2-15
Managing Alarms	2-16
Connecting to Power	2-17

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INTRODUCTION

The LIFEPAK 20 defibrillator/monitor is an acute cardiac care response system used by authorized healthcare providers in hospital and clinic settings.

The LIFEPAK 20 defibrillator/monitor offers the following optional features:

- Semiautomatic defibrillator
- Noninvasive pacemaker
- Pulse oximeter
- Paddle accessories

Note: These operating instructions include information and procedures related to all features of the LIFEPAK 20 defibrillator/monitor. Your LIFEPAK 20 defibrillator/monitor may not have all of these features. For more information, contact your Medtronic representative or call the number listed on page ii of these operating instructions.

The LIFEPAK 20 defibrillator/monitor is available only with the biphasic defibrillation waveform. For a description of the defibrillation waveform, refer to Appendix A.

The LIFEPAK 20 defibrillator/monitor uses QUIK-COMBO™ pacing/defibrillation/ECG electrodes or FAST-PATCH® disposable defibrillation/ECG electrodes for ECG monitoring and patient therapy. The therapy cable connects the QUIK-COMBO or FAST-PATCH electrodes to the defibrillator. For more information about QUIK-COMBO or FAST-PATCH electrodes, refer to Section 3 of these operating instructions.

The standard paddle set is an accessory for the LIFEPAK 20 defibrillator/monitor and includes adult and pediatric defibrillator (hard) paddles. The standard paddles can be used for QUIK-LOOK® ECG monitoring, defibrillation, and synchronized cardioversion therapies. When using standard paddles, a conductive interface designed for defibrillation, such as defibrillation gel or gel pads, must be used between the paddle electrode surface and the skin.

The adult standard paddles can be used for any pediatric patient weighing approximately 10 kg (22 lb) or more as long as the paddles fit completely on the chest and there is at least 2.5 cm (1 in.) of space between the paddle electrodes. Pediatric paddles should be used for patients weighing 10 kg (22 lb) or less or those whose chests are too small to accommodate the adult paddles.

Optional posterior, internal, and external sterilizable paddles accessories are also available.

For more information about using paddle accessories, refer to Section 5 of these operating instructions.

UNPACKING AND INSPECTING

Once you have removed the LIFEPAK 20 defibrillator/monitor from the shipping container, examine the device and all accessories for any sign of damage. Make sure you have all the required supplies and accessories including cables and ECG paper. Save the shipping container and foam inserts for possibly shipping the device at a later date.

CONTROLS, INDICATORS, AND CONNECTORS

The following figures provide a brief description of the controls, indicators, and connectors for the LIFEPAK 20 defibrillator/monitor. Figure 2-1 shows the front view of the LIFEPAK 20 defibrillator/monitor divided into six areas. Figure 2-3 through Figure 2-12 show details of each area. Figure 2-13 shows the back view of the defibrillator. Additional information about areas 3, 4, and 6 follow the applicable figures. The light emitting diode (LED) in a function button is on when the corresponding function is active. For example, the ANALYZE button LED is on when the advisory function is active.

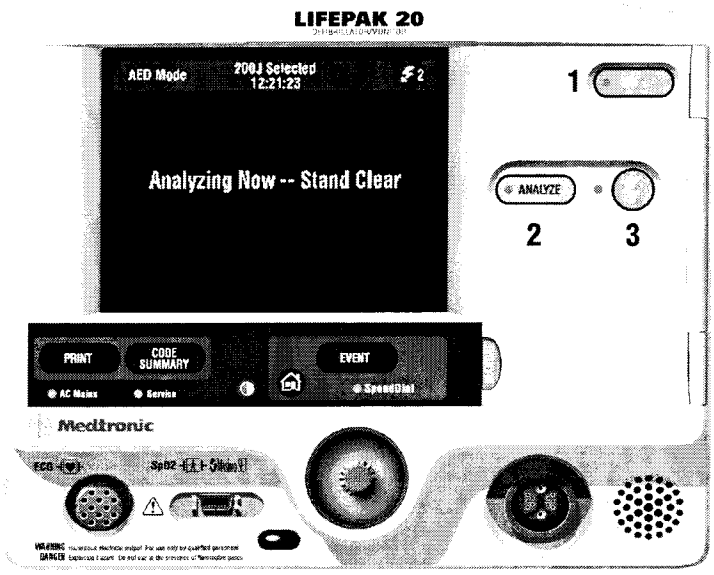

Figure 2-1 Front View with Door

The door on the LIFEPAK 20 defibrillator/monitor hides the manual defibrillation and noninvasive pacing buttons. When the door is closed, the appearance and operation of the device is simplified for the automated external defibrillator (AED) user.

To enter manual mode, press the MANUAL button located on the lower left corner of the door. This opens the door and automatically takes the device out of AED mode and allows access to manual mode defibrillation and pacing. After entering manual mode, closing the door does not affect operation.

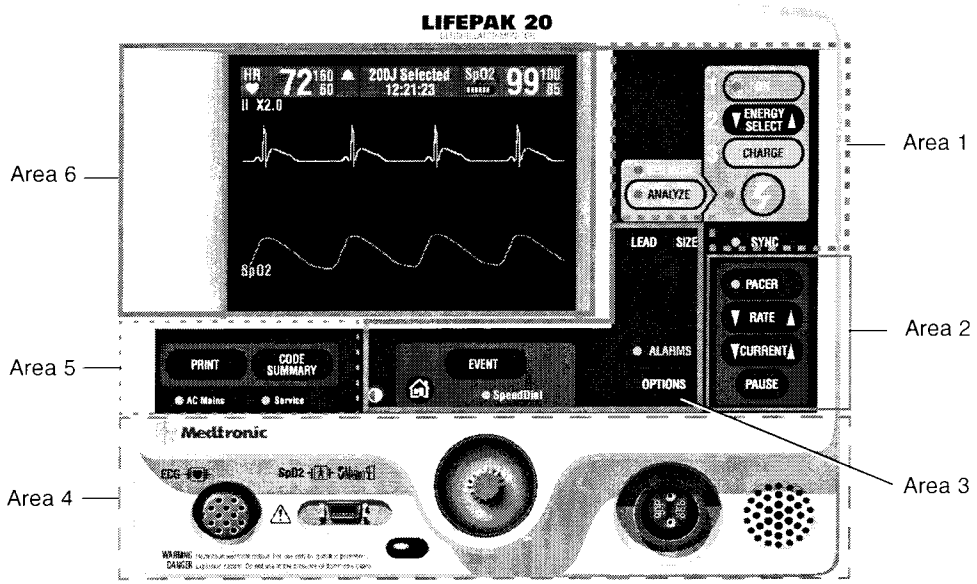

Figure 2-2 Front View without Door

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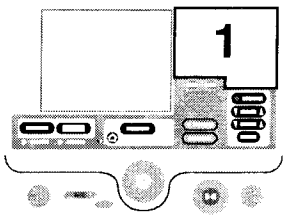
Area 1



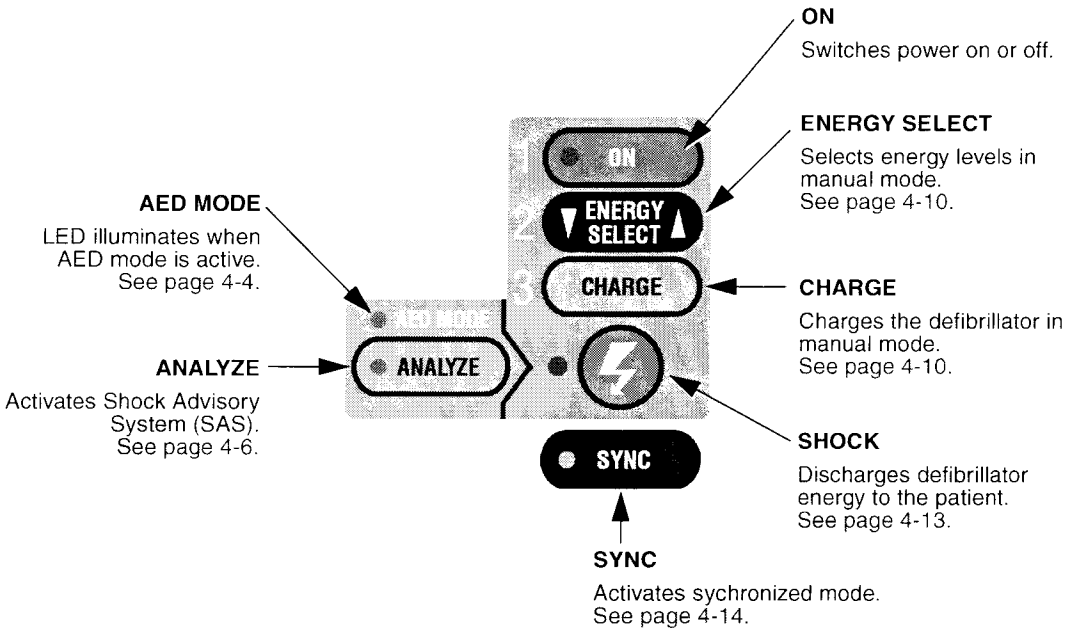
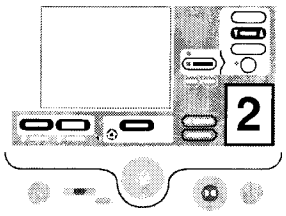
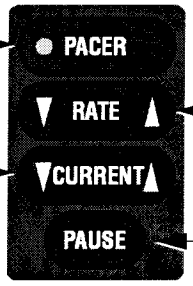


Figure 2-3 Area 1

Area 2





PACER

Activates the pacing function.
See page 4-19.

CURRENT

Adjusts pacing current.
See page 4-19.

RATE

Selects pacing rate.
See page 4-19.

PAUSE

Temporarily slows pacing rate.
See page 4-19.

Figure 2-4 Area 2

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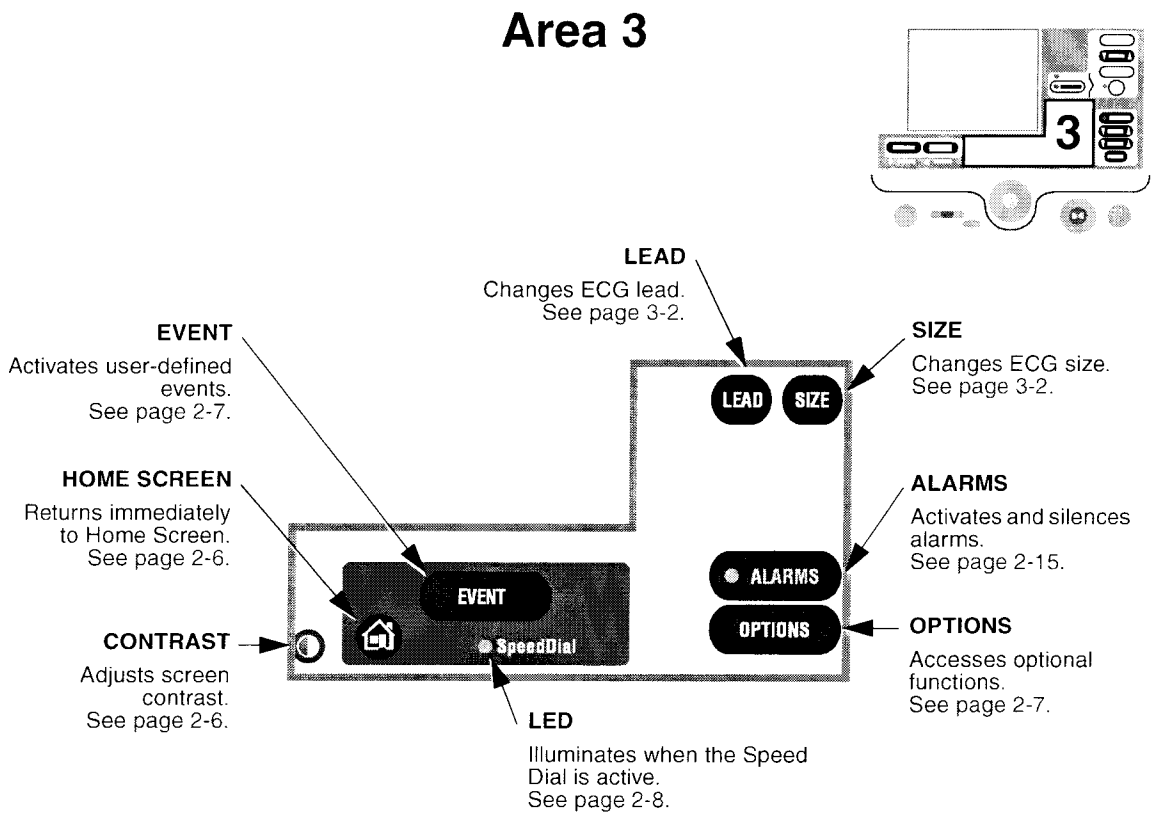


Figure 2-5 Area 3

Area 3

The following paragraphs provide additional information about the controls shown in Area 3, page 2-6.

Contrast (Passive Display Only)

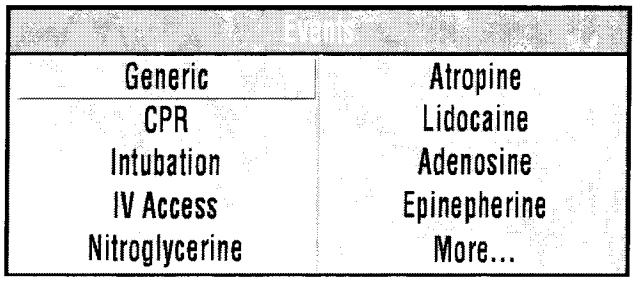
Press the CONTRAST button and rotate the Speed Dial to adjust the screen contrast/brightness. When the defibrillator is turned on, the contrast setting defaults to the previously adjusted setting.

Home Screen

The home screen is the background screen that displays during ECG monitoring. Pressing HOME SCREEN returns you to the home screen from any menu screen or overlay, except during AED analysis or during manual defibrillation charging and shocking.

Event

After pressing EVENT, the screen displays the following overlay.



Use the Speed Dial to scroll through and select menu choices.

Generic is automatically selected when EVENT is pressed and no other selection is made. The selected event and time stamp appear in the message/status area on the screen. Events are printed in the CODE SUMMARY™ Event Log. Refer to page 8-7 for information about configuring events.

Options

After pressing OPTIONS, the screen displays the overlay shown in Figure 2-6. Use the Speed Dial to scroll through and select menu choices.

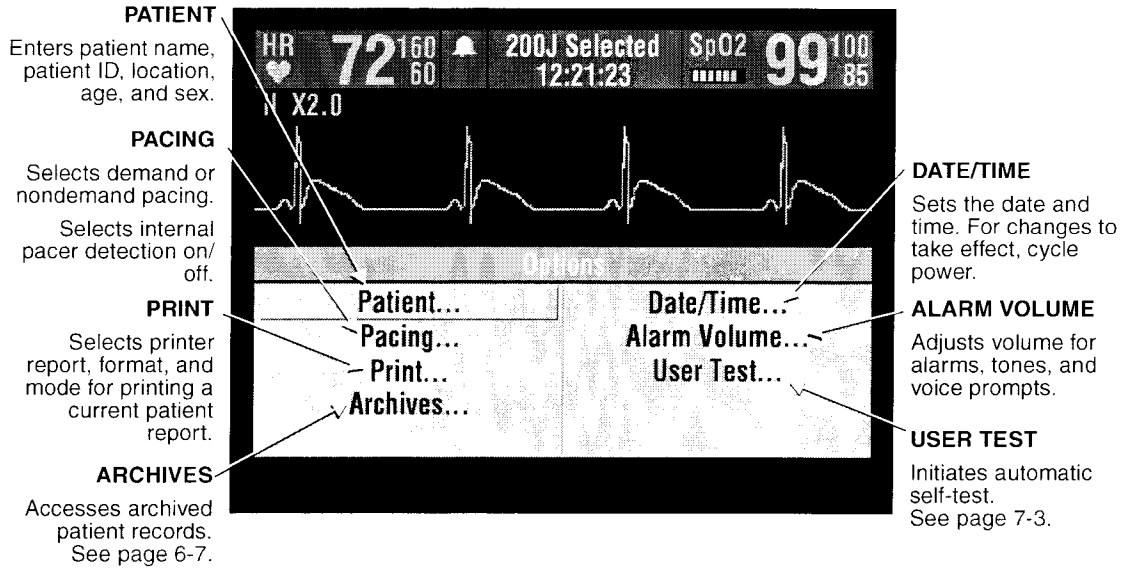


Figure 2-6 Options

Alarms

Refer to page 2-15 for information about setting alarms.

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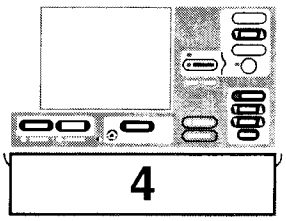
Area 4



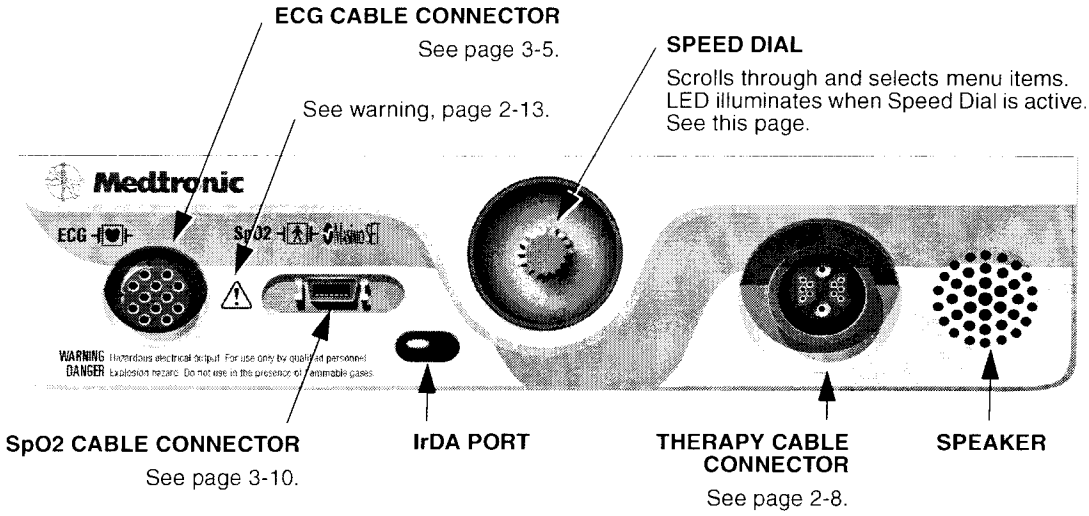


Figure 2-7 Area 4

Area 4

The following paragraphs provide additional information about the Speed Dial and the therapy cable connector shown in Area 4.

Speed Dial

The Speed Dial is active when the indicator LED is illuminated. When active, you can rotate the Speed Dial to highlight and select certain areas of the screen and displayed menu items. Pressing the Speed Dial activates the highlighted menu item. Default menu items are highlighted with a gray background; after a menu item is selected, the background is black.

Therapy Cable Connector

WARNING!

Possible equipment damage and inability to deliver therapy.

To protect the therapy cable connector from damage or contamination, keep the therapy cable connected to the defibrillator at all times.

Connecting the Therapy Cable

To connect a therapy cable to the therapy cable connector:

1 Orient the therapy cable so that the arrow is on top with the cable angled to the right (see Figure 2-8).
2 Insert the therapy cable into the therapy cable connector on the defibrillator.
3 Rotate the locking ring on the therapy cable clockwise until you feel the connector "click." Pull gently on the locking ring to check that the cable is locked in place.

Disconnecting the Therapy Cable

To disconnect a therapy cable from the defibrillator:

1 Rotate the locking ring on the therapy cable in the direction of the arrow (counterclockwise) until it stops (see Figure 2-9).
2 Gently pull out the cable.

Note: LIFEPAK 20 defibrillator/monitors with hardwired standard paddles do not have this feature.

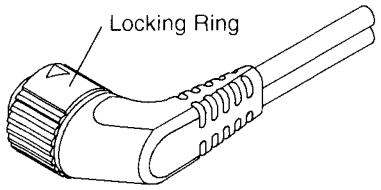


Figure 2-8 Therapy Cable Orientation

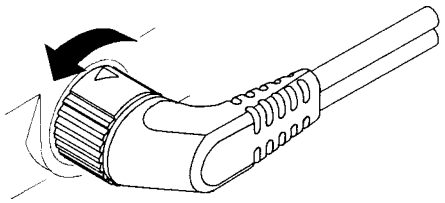
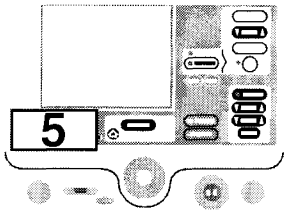
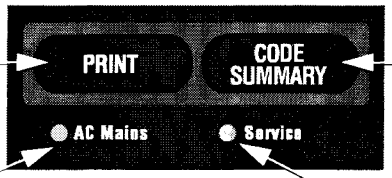


Figure 2-9 Disconnecting the Therapy Cable

Area 5





PRINT
Starts or stops the printer.

AC MAINS
LED illuminates when ac power (line power) is connected and providing power. Internal battery is charging.

CODE SUMMARY
Prints a CODE SUMMARY critical event record.
See page 6-2.

SERVICE
Indicates that service is required.

Figure 2-10 Area 5

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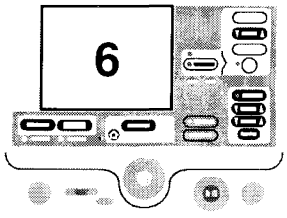
Area 6

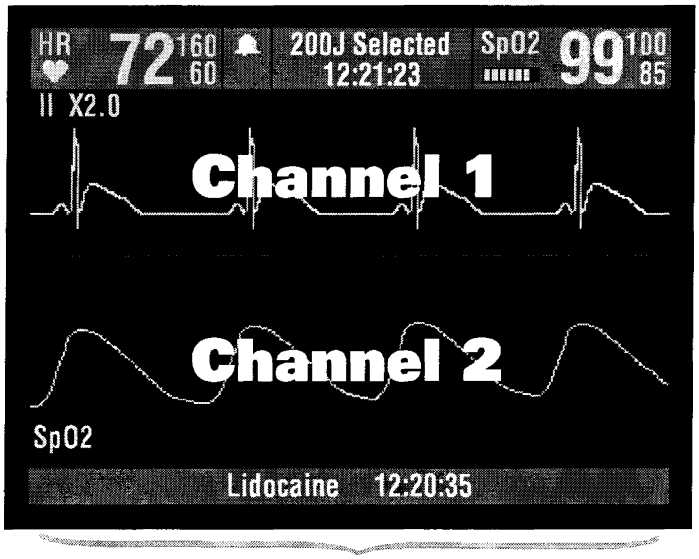


MONITORING AREA

Displays heart rate, time, SpO2, indicators for VF/VT alarm and selected energy. See page 2-11.

WAVEFORM CHANNEL AREA

Displays up to two waveform channels. See page 2-11.



STATUS MESSAGE AREA

Displays status and alarm messages.

Figure 2-11 Area 6

Area 6

The following paragraphs provide additional information about Area 6.

Monitoring Area—Heart Rate

The LIFEPAK 20 defibrillator/monitor displays a heart rate between 20 and 300 beats per minute (bpm). A heart rate symbol flashes with each beat. If the heart rate is below 20 bpm or pacing is enabled, the screen displays dashes (– – –). Heart rates above 300 bpm do not yield valid systole tones and the displayed heart rate will not be valid. The heart rate indicator is a tool to be used in addition to patient assessment. Care should be taken to assess the patient at all times and not to rely solely on the heart rate displayed.

WARNING!

Failure to detect a change in ECG rhythm.

Heart rate meters may continue to count the internal pacing pulses during occurrences of cardiac arrest or some arrhythmias. Do not rely entirely on heart rate meter alarms. Keep pacemaker patients under close surveillance.

QRS detection is essential for using the digital heart rate display, systole tone, synchronized cardioversion, and noninvasive demand pacing. The QRS detector in the LIFEPAK 20 defibrillator/monitor selectively detects QRS complexes. It discriminates against most noise, muscle artifact, T-waves, and other spurious signals.

The QRS detect algorithm automatically adjusts itself to the amplitude of the QRS complexes. Changing the gain of the ECG has no effect on QRS detection. For optimum QRS detection performance, use the lead with the greatest QRS amplitude.

Monitoring Area—Pulse Rate. If the ECG is not active, the SpO2 monitor can display pulse rate. The pulse rate source is indicated by PR (SPO2).

Monitoring Area—SpO2 (pulse oximeter). The oxygen saturation level is shown as a percentage from 50 to 100. Saturation below 50% is shown as <50%. A fluctuating bar graph represents the pulse signal strength.

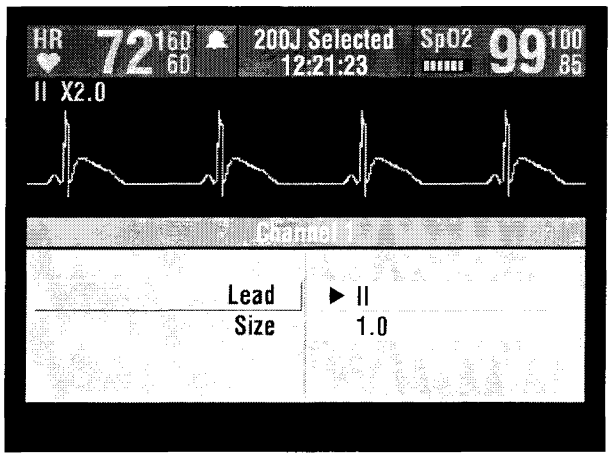
Waveform Channel Area

Channel 1. This is the top channel. It displays the primary ECG waveform and is always visible when ECG is displayed.

Channel 2. This is the bottom channel. It can display an additional waveform or a continuation of the Channel 1 ECG.

Selecting Waveform Channels

The monitor power must be turned on.



1 At the home screen, rotate the Speed Dial to highlight Channel 1 or 2.
2 Press the Speed Dial. An overlay appears with the monitoring choices for the selected channel.
3 Rotate and press the Speed Dial to select monitoring choices for that channel.

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Changing Printer Paper

CAUTION!

Possible printer malfunction.

Using other manufacturers' printer paper may cause the printer to function improperly and/or damage the print head. Use only the printer paper specified in these operating instructions.

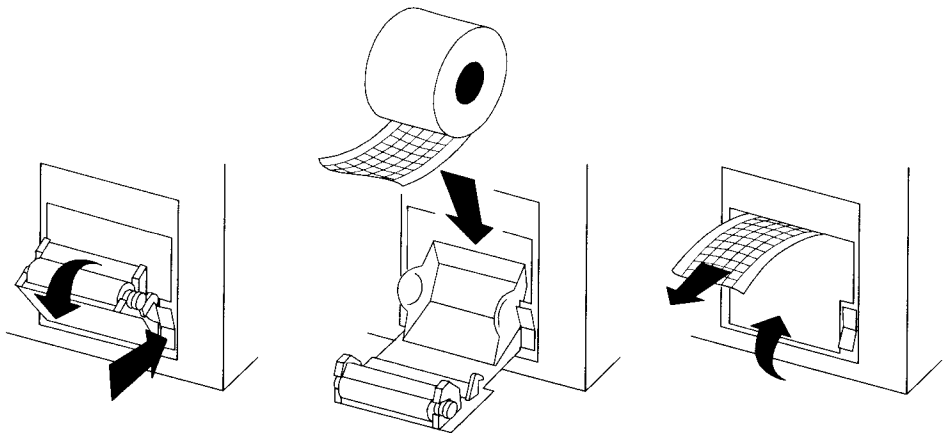
Loading 50 mm Paper (PN 804700)

The printer is equipped with an out-of-paper sensor to protect the printhead. The sensor automatically turns off the printer if paper runs out or if the printer door is open.

To load the paper:

1 Press the black button to open the printer door.
2 Remove the empty paper roll.
3 Insert the new paper roll, grid facing upward.
4 Pull out a short length of paper.
5 Push the printer door in to close.

Figure 2-12 illustrates the steps for loading 50 mm paper.



igure 2-12 Printer

Back View

The following paragraphs provide additional information about the back view (see Figure 2-13).

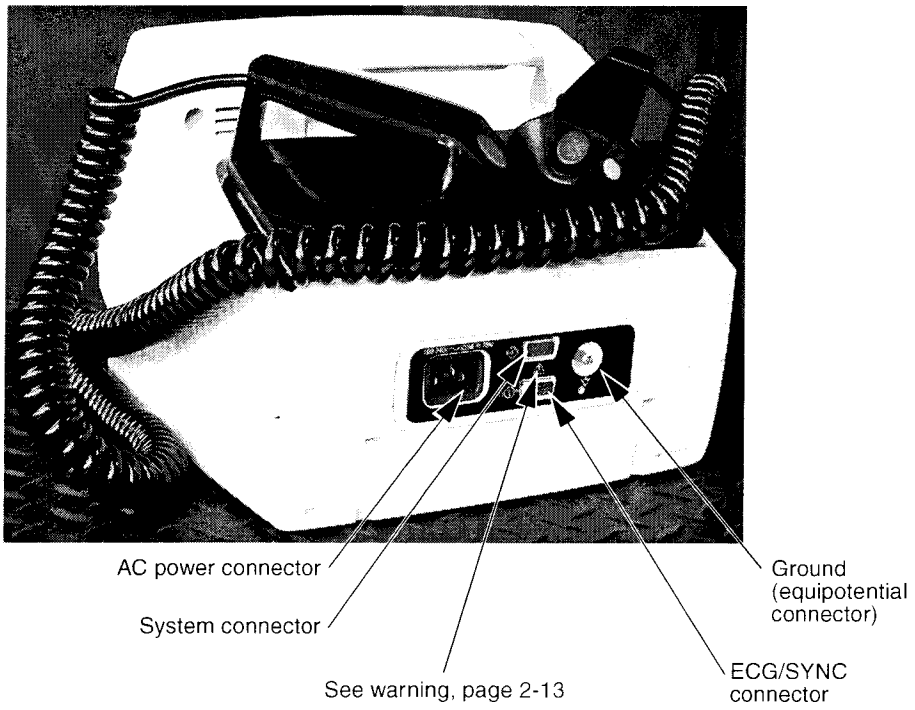


Figure 2-13 Back View

WARNING!

Shock hazard.

If you are monitoring a patient and using the system connector, all equipment connected to the system connector must be battery powered or electrically isolated from ac power according to EN 60601-1. If in doubt, disconnect the patient from the monitor before using the system connector. For more information, contact Medtronic Technical Support.

System Connector

The system connector allows you to connect the LIFEPAK 20 defibrillator/monitor to a computer for sending patient reports. The system connector also allows access to another LIFEPAK 20 defibrillator/monitor, so that setup information can be transferred between devices.

ECG/SYNC Connector

The ECG/SYNC connector provides remote synchronization and real-time ECG output to a third party monitor.

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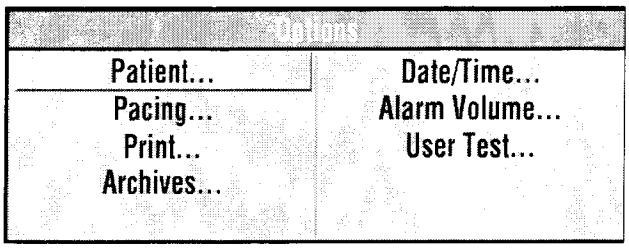
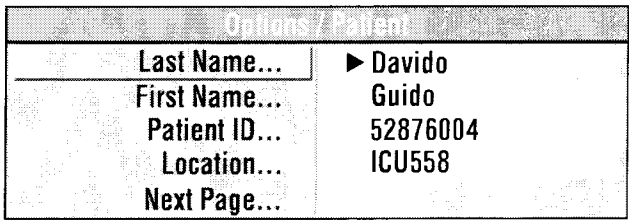
ENTERING PATIENT DATA

The following paragraphs describe how to enter or edit a patient's name, identification (ID), age, or sex.

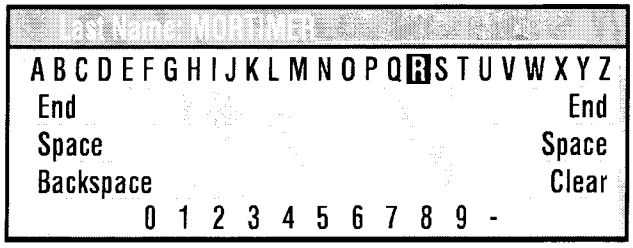


1 Press OPTIONS.
2 Select PATIENT.

To enter or edit a patient's name or ID:



1 Select LAST NAME, FIRST NAME, or ID. LAST NAME is used as an example (for this procedure).

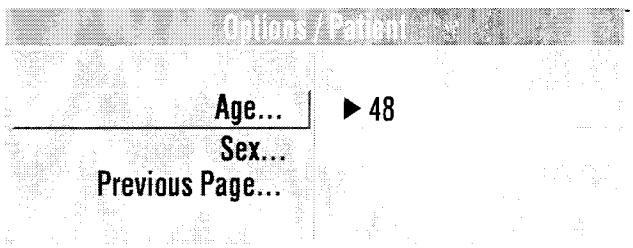


2 Rotate the Speed Dial to scroll through the alphabet.
3 Press the Speed Dial to select the desired character. The character appears in the highlighted area.
4 Repeat steps 2 and 3 until the name is complete.
5 Scroll and select END to return to the Options/Patient screen as shown previously.

There are three additional commands: BACKSPACE – moves highlight bar left one space
CLEAR – clears all characters in the name field
SPACE – inserts a blank space

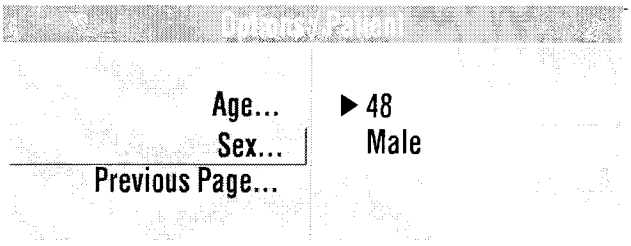
6 To exit, press the OPTIONS or HOME SCREEN button.

To enter or edit a patient's age:



1 Select AGE.
2 Rotate the Speed Dial to scroll to the desired age.
3 Press the Speed Dial.

To enter or edit a patient's sex:



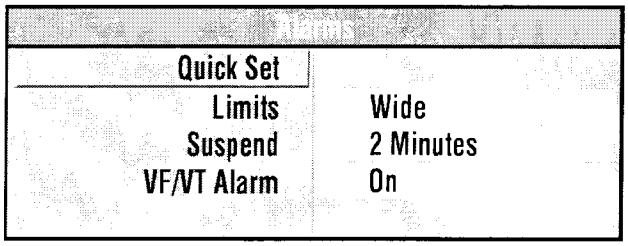
1 Select SEX.
2 Rotate the Speed Dial to highlight MALE or FEMALE.
3 Press the Speed Dial.

SETTING ALARMS

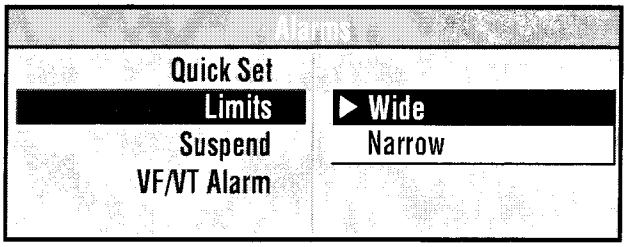
Alarms for the LIFEPAK 20 defibrillator/monitor can be configured to ON or OFF, and are enabled when the monitor is turned on. When the alarms are configured ON, predetermined limits are set. To view these limits, press the ALARMS button. The limits will appear to the right of the parameter value. To change the limits, select QUICK SET.

When the alarms are configured OFF, the ALARMS button must be pressed and QUICK SET selected to enable alarms.

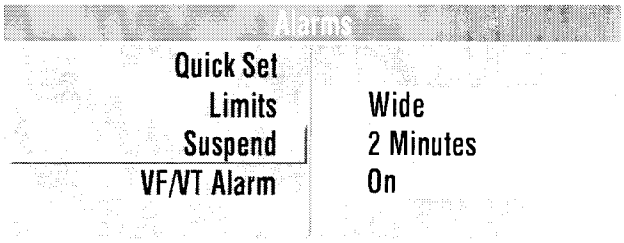
When you press the ALARMS button, the following Alarms overlay appears:



1 Select QUICK SET to activate the alarms for all active parameters. The quick set limits are set automatically based on the patient's current vital sign values (refer to Table 2-1). The alarm limits default to the setting (WIDE or NARROW) displayed on the overlay.



2 Select LIMITS to change the alarm limits to WIDE or NARROW (refer to Table 2-1).



3 Select SUSPEND to turn off the audible alarm for up to 15 minutes. If an alarm limit is exceeded while the alarm is silenced, the violated parameter flashes, an alarm message appears, but the alarm tone remains silent.

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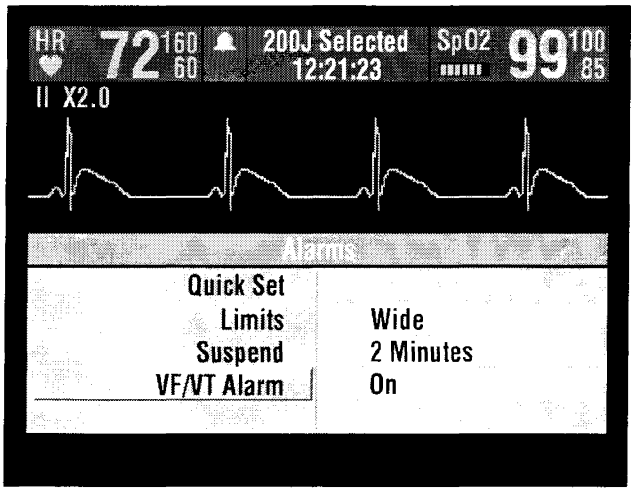

Select VF/VT ALARM to turn on continuous monitoring for ventricular fibrillation and ventricular tachycardia in manual mode.

A symbol appears above the primary ECG when the alarm is on .

Reselect VF/VT ALARM to turn off this alarm.

Note: When the VF/VT alarm is on, you are limited to paddles lead or lead II. Refer to Selecting ECG Lead and Size, page 3-2.

Note: The VF/VT alarm will be suspended when the noninvasive pacemaker is on and when standard paddles are attached and PADDLES LEAD is selected. The alarm is also suspended when the device is charging or is fully charged.

Table 2-1 Wide and Narrow Alarm Limits

Parameter	Range	Wide Limits[1]		Narrow Limits[1]		Limits Range[2]	
		Low	High	Low	High	Low	High
Heart Rate (bpm)	<60	-20	+35	-10	+25	30–150	100–250
	60–79	-25	+40	-20	+30		
	80–104	-30	+40	-30	+30		
	≥105	-35	+45	-25	+25		
SpO2 (%)	≥90	-5	+3	-5	+3	50	90–100
	<90	-5	+3	-5	+3		

Numbers are ± from patients' initial value

Numbers are absolute range values

MANAGING ALARMS

The alarm bell symbol indicates when alarms are on or off . When alarms are on and an alarm limit is exceeded, a tone sounds, the violated parameter flashes, and an alarm message appears.

To manage an alarm:

1. Press ALARMS. This silences the alarm for 2 minutes.
2. Assess the cause of the alarm.
3. Assess the appropriateness of the limits setting (WIDE or NARROW).
4. If the patient is unstable, consider silencing the alarm for up to 15 minutes while attending to the patient. Do **not** reselect QUICK SET.
5. Once the patient is stable, reselect QUICK SET if necessary.

WARNING!

Possible failure to detect an out of range condition.

Reselecting QUICK SET will reset the alarm limits around the patient's current vital sign values. This may be outside the safe range for the patient.

When alarms are on, you can silence them preemptively for up to 15 minutes.

To silence alarms preemptively:

1 Press ALARMS.
2 Select SUSPEND.
3 Select a silence duration of 2, 5, 10, or 15 minutes.
4 The message *ALARMS SUSPENDED* appears on the bottom of the screen.

CONNECTING TO POWER

The LIFEPAK 20 defibrillator/monitor operates on ac (line) power or its internal battery. You can switch from battery to ac power or ac power to battery while the device is on and in use by plugging in or unplugging the ac power cord.

WARNING!

Possible defibrillator shutdown.

When operating on battery power, the large current draw required for defibrillator charging may cause the defibrillator to reach shutdown voltage levels with no low battery warning. If the defibrillator shuts down without warning, or if a *LOW BATTERY. CONNECT TO AC POWER* message appears on the monitor screen, immediately connect the ac power cord to an outlet.

AC Operation

When the LIFEPAK 20 defibrillator/monitor is operating on ac power, the AC Mains LED on the front panel illuminates and the battery charges until fully charged. When the device is not being used, the battery charge will be maintained only if the power cord is connected to an ac outlet with the device turned off.

Battery Operation

The LIFEPAK 20 defibrillator/monitor automatically operates on battery power when the power cord is disconnected from an ac outlet or the device. A new fully charged battery provides approximately 90 360 J discharges, 70 minutes of pacing, or approximately 120 minutes of continuous monitoring before the device powers off. When the *LOW BATTERY. CONNECT TO AC POWER* message appears on the monitor screen, immediately plug the power cord into an ac outlet to continue use. This supplies power and begins recharging the battery. Frequently occurring low battery messages indicate that the battery may need to be replaced. Contact Medtronic Technical Service or qualified service personnel to replace the battery.

Always connect the device to ac power after use to recharge depleted batteries to full capacity. A fully-depleted battery requires two hours of charge time to regain full capacity. Partially depleted batteries require a recharge time equivalent to the time the device was in use; for example, if the device was in use for one hour, the required recharge time will be one hour.

New batteries, or batteries that have been stored for a prolonged time, need to be recharged prior to use by connecting the device to an ac outlet to bring the battery to full charge.

The LIFEPAK 20 defibrillator/monitor may be configured to issue a series of warning beeps, AC LOSS ALERT, if the device is off and not connected to an ac power source. Refer to the service manual for further directions.

For further information regarding battery performance, refer to Specifications and Performance Characteristics, Appendix A.

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Battery Life

The LIFEPAK 20 defibrillator/monitor has a nickel-metal hydride battery that is intended to be used for standby operation. To help obtain maximum battery performance, keep your defibrillator/monitor plugged in to an ac outlet when not in use. Frequent use of the battery when it is at minimum reserve capacity will reduce the battery life. End of battery life is inevitable. As batteries age, their charge capacities diminish. The defibrillator/monitor battery should be replaced every two years as a preventive maintenance measure.

MONITORING

This section describes the monitoring features of the LIFEPAK 20 defibrillator/monitor.

Monitoring the ECG	page 3-2
Monitoring SpO2	3-8

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MONITORING THE ECG

The following subsections describe:

- ECG Monitoring Warning
- Selecting ECG Lead and Size
- Adjusting the Systole Tone Volume
- Monitoring ECG with Paddles Accessories
- Monitoring with the Patient ECG Cable
- Troubleshooting Tips for ECG Monitoring

ECG Monitoring Warning

WARNING!

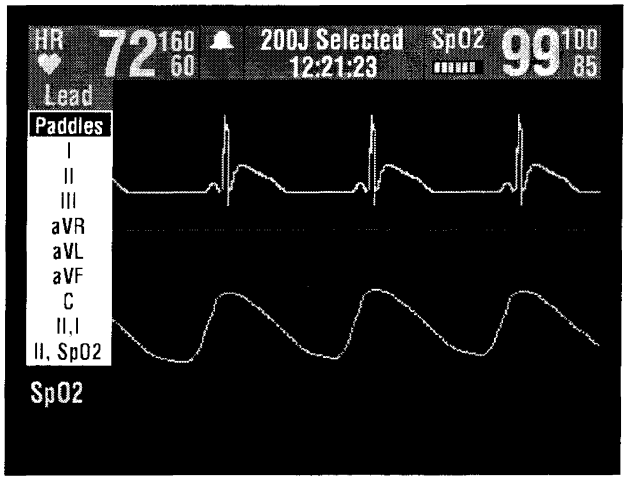
Possible misinterpretation of ECG data.

The frequency response of the monitor screen is intended only for basic ECG rhythm identification; it does not provide the resolution required for diagnostic and ST segment interpretation. For diagnostic or ST segment interpretation, or to enhance internal pacemaker pulse visibility, attach the ECG cable. Then print the ECG rhythm in diagnostic frequency response (DIAG).

Selecting ECG Lead and Size

There are two methods for selecting or changing the ECG lead. Both methods are available on your LIFEPAK 20 defibrillator/monitor. The leads available depend on the ECG cable (3-wire or 5-wire) connected to the device.

To change the ECG lead using the LEAD button:



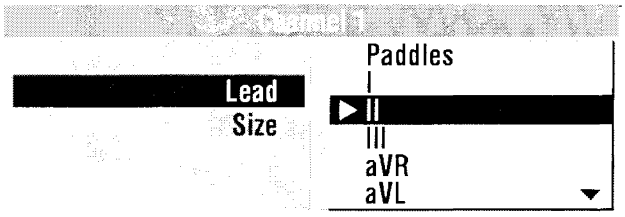
1 Press the LEAD button. If an ECG lead appears, the lead automatically changes to paddles. If paddles lead appears, the lead automatically changes to lead II.

2 When the Lead menu appears, press the LEAD button again or rotate the Speed Dial to select another lead. The highlighted selection shows the ECG lead.

Note: When the VF/VT alarm is on, you are limited to paddles lead or lead II in Channel 1. Refer to Setting Alarms, page 2-15.

Note: If one or more lead sets are preconfigured, the menu will display the lead sets. Refer to page 3-7 for information about configuring lead sets.

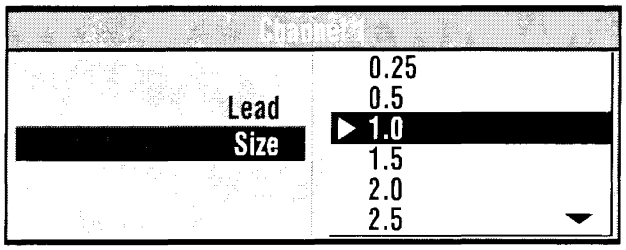
To select or change the ECG lead using the Speed Dial:



1 Highlight and select Channel 1 and then Lead to obtain the primary ECG lead choices.
2 Change ECG lead by rotating the Speed Dial. The highlighted selection shows the ECG lead.
3 Repeat steps 1 and 2 to select or change displayed waveforms for Channel 2.

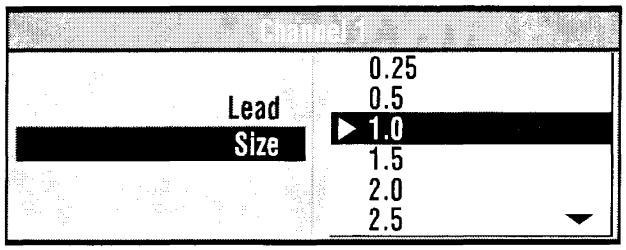
You can select or change the ECG size by using the SIZE button or the Speed Dial. If an ECG is in Channel 2, the size is automatically changed to match the Channel 1 size.

To select or change the ECG size using the SIZE button:



1 Press the SIZE button.
2 When the Size menu appears, press the SIZE button again or rotate the Speed Dial. The highlighted selection shows the current ECG size.

To select or change the ECG size using the Speed Dial:

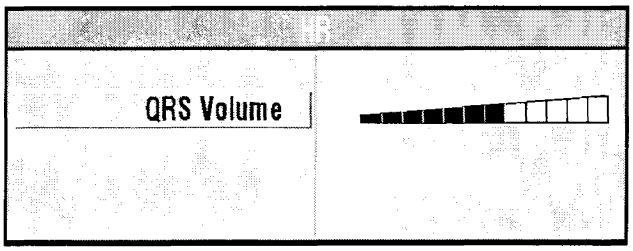


1 To obtain the primary ECG, highlight and select Channel 1 and then Size.
2 Change ECG size by rotating the Speed Dial. The highlighted selection shows the current ECG size.

Adjusting the Systole Tone Volume

To adjust the systole tone volume, highlight and select heart rate (HR) in the monitoring area of the screen.

The following overlay appears:



1 Rotate the Speed Dial to the desired volume.
2 Press the home screen to exit.

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Monitoring ECG with Paddles Accessories

Anterior-lateral Placement

Anterior-lateral placement is the only placement that should be used for ECG monitoring with paddles accessories.

1 Place either the ♥ or + therapy electrode or the apex paddle lateral to the patient's left nipple in the midaxillary line, with the center of the electrode in the midaxillary line, if possible. See Figure 3-1.

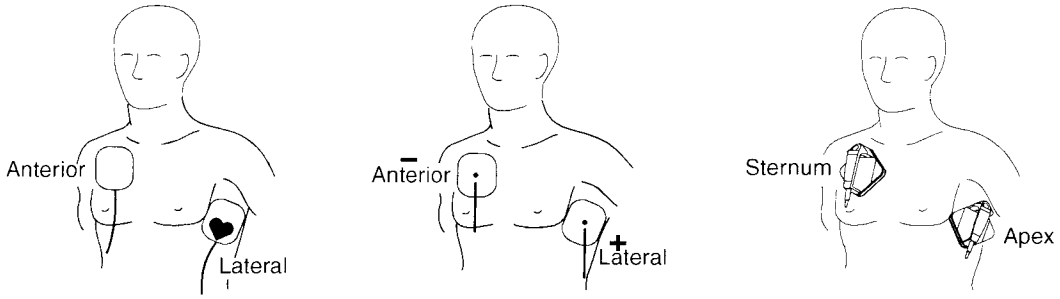


Figure 3-1 Anterior-lateral Placement

2 Place the other therapy electrode or sternum paddle on the patient's upper right torso, lateral to the sternum and below the clavicle as shown in Figure 3-1.

Special Placement Situations

When placing therapy electrodes or standard paddles, be aware of the special requirements in the following possible situations.

Obese Patients or Patients with Large Breasts

Apply therapy electrodes or standard paddles to a flat area on the chest, if possible. If skin folds or breast tissue prevent good adhesion, it may be necessary to spread skin folds apart to create a flat surface.

Thin Patients

Follow the contour of the ribs and spaces when pressing the therapy electrodes or standard paddles onto the torso. This limits air spaces or gaps under the electrodes and promotes good skin contact.

Patients with Implanted Pacemakers

If possible, place therapy electrodes or standard paddles away from internal pacemaker generator.

Patients with Implanted Defibrillators

Apply therapy electrodes or standard paddles in the anterior-lateral position and treat this patient as any other patient requiring emergency care.

Paddles Monitoring Procedure

To monitor using therapy electrodes or standard paddles:

Press ON. Adjust contrast if necessary.

2 Prepare the patient's skin:

- Remove excessive chest hair as much as possible. Avoid nicking or cutting the skin. If possible, avoid placing therapy electrodes or standard paddles over broken skin.
- Clean and dry the skin.
- Do not use alcohol, tincture of benzoin, or antiperspirant to prep the skin.

3 Apply the therapy electrodes or standard paddles in the anterior-lateral position.
For therapy electrodes, confirm that the package is sealed and the Use By date has not passed. For standard paddles, apply conductive gel over the entire electrode surface.
4 Connect the disposable therapy electrodes to the therapy cable.
5 Select paddles lead.

Monitoring with the Patient ECG Cable

There are two ECG cables available for ECG monitoring as shown in Figure 3-2: the 3-wire and 5-wire cables.

Connecting the Patient ECG Cable

Connect the cable by inserting the main cable connector into the green electrically isolated ECG connector on the monitor.

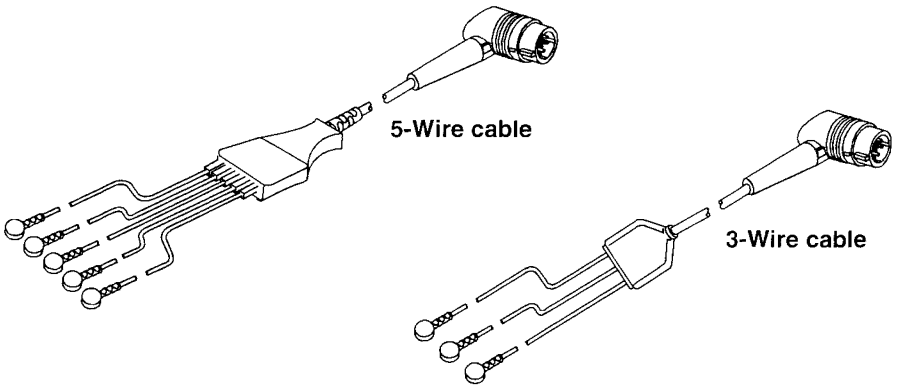
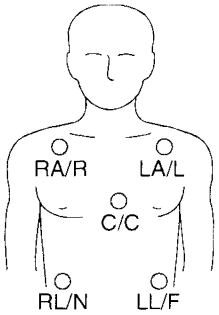


Figure 3-2 3-wire and 5-wire ECG Cables

ECG Monitoring Procedure

1 Press ON. Adjust contrast if necessary.
2 Attach the ECG cable to the monitor.
3 Identify the appropriate electrode sites on the patient as shown in Figure 3-3.



AHA Labels		IEC Labels	
RA	Right Arm	**R**	Right
LA	Left Arm	**L**	Left
RL*	Right Leg	**N**	Negative
LL	Left Leg	**F**	Foot
C*	Chest	**C**	Chest

***Note**: Not used for 3-wire cable.

Figure 3-3 Electrode Placement for ECG monitoring

4 Prepare the patient's skin for electrode application:
- Shave excessive hair at electrode site. Avoid locating electrodes over tendons and major muscle masses.
- For oily skin, clean skin with an alcohol pad.
- Dry the site with a brisk rub.

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5 Apply ECG electrodes:
   - Confirm package is sealed and Use By date has not passed.
   - Attach an electrode to each of the lead wires.
   - Grasp electrode tab and peel electrode from carrier.
   - Inspect electrode gel and ensure the gel is intact (discard electrode if gel is not intact).
   - Hold electrode taut with both hands. Apply the electrode flat to the skin. Smooth tape outwardly. Avoid pressing the center of the electrode.
   - Secure the trunk cable clasp to the patient's clothing.
6 Select the lead on the monitor screen.
7 If necessary, adjust ECG size.
8 Press PRINT to obtain an ECG printout.

ECG Electrode Requirements

Electrode quality is critical for obtaining an undistorted ECG signal. Always check the date code on electrode packages for the Use By date before applying the electrodes to a patient. Do not use electrodes with expired Use By date codes. Disposable electrodes are intended for a single use.

For best ECG monitoring results, use silver/silver chloride (Ag/AgCl) electrodes such as Medtronic LIFE•PATCH® ECG electrodes. The post-defibrillation ECG will display in less time than expected with other types of electrodes.

Leads Off Messages

If an electrode or lead wire disconnects during ECG monitoring, the monitor emits an audible alarm and displays a leads off message. The ECG trace becomes a dashed line. The alarm and messages continue until the electrode or lead wire is replaced.

Color Coding for ECG Leads

The lead wires and the electrode snaps for the patient ECG cable are color coded according to AHA or IEC standards as listed in Table 3-1.

Table 3-1 ECG Leads Color Codes

Leads	AHA Label	AHA Color	IEC Label	IEC Color
Limb Leads	RA	White	R	Red
	LA	Black	L	Yellow
	RL	Green	N	Black
	LL	Red	F	Green
	C	Brown	C	Brown

Monitoring Patients with Internal Pacemakers

The LIFEPAK 20 defibrillator/monitor typically does not use internal pacemaker pulses to calculate the heart rate. However, the monitor may detect internal pacemaker pulses as QRS complexes. This may result in an inaccurate heart rate display.

Smaller amplitude internal pacemaker pulses may not be distinguished clearly. For improved detection and visibility of internal pacemaker pulses, turn on the internal pacemaker detector, and/or connect the ECG cable, select an ECG lead, and print the ECG in diagnostic frequency response.

Large amplitude pacemaker pulses may overload the QRS complex detector circuitry so that no paced QRS complexes are counted. To help minimize ECG pickup of large unipolar pacemaker pulses when monitoring patients with internal pacemakers, place ECG electrodes so the line between the positive and negative electrodes is perpendicular to the line between the pacemaker generator and the heart.

The LIFEPAK 20 defibrillator/monitor annotates internal pacemaker pulses with a hollow arrow ⇧ on the display and the printed ECG if this feature is configured or selected ON. False annotations of this arrow may occur if ECG artifacts mimic internal pacer pulses. If false annotations occur, you may deactivate the detection feature using the Options/Pacing/Internal Pacer menu (see Figure 2-6). Also refer to the Pacing Setup Menu in Table 8-7. Patient history and other ECG waveform data, such as wide QRS complexes, should be used to verify the presence of an internal pacemaker.

Troubleshooting Tips for ECG Monitoring

If problems occur while monitoring the ECG, check the list of observations in Table 3-2 for aid in troubleshooting. For basic troubleshooting problems such as no power, refer to General Troubleshooting Tips in Section 7.

Table 3-2 Troubleshooting Tips for ECG Monitoring

Observation	Possible Cause	Corrective Action
1 Screen blank and ON LED lighted.	Screen not functioning properly.	• Print ECG on recorder as backup. • Contact service personnel for repair.
2 Any of these messages displayed: CONNECT ELECTRODES CONNECT ECG LEADS ECG LEADS OFF XX LEADS OFF	Therapy electrodes are not connected.	• Confirm therapy electrode connections.
	One or more ECG electrodes are disconnected.	• Confirm ECG electrode connections.
	ECG cable is not connected to monitor.	• Confirm ECG cable connections.
	Poor electrode-to-patient adhesion.	• Reposition cable and/or lead wires to prevent electrodes from pulling away from patient. • Prepare skin and replace electrode(s). • Select another lead.
	Broken ECG cable lead wire.	• Select paddles lead and use standard paddles or therapy electrodes for ECG monitoring. • Check ECG cable continuity.
3 Poor ECG signal quality.	Poor electrode-skin contact.	• Reposition cable and/or lead wires to prevent electrodes from pulling away from patient. Secure trunk cable clasp to patient's clothing. • Prepare skin and replace electrode(s).
	Outdated, corroded, or dried-out electrodes.	• Check date codes on electrode packages. • Use only silver/silver chloride electrodes with Use By dates that have not passed. • Leave electrodes in sealed pouch until time of use.
	Loose connection. Damaged cable or connector/lead wire.	• Check/reconnect cable connections. • Inspect ECG and therapy cables. • Replace if damaged. • Check cable with simulator and replace if malfunction observed.
	Noise because of radio frequency interference (RFI).	• Check for equipment causing RFI (such as a radio transmitter) and relocate or turn off equipment power.

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Table 3-2 Troubleshooting Tips for ECG Monitoring (Continued)

Observation	Possible Cause	Corrective Action
4 Baseline wander (low frequency/high amplitude artifact).	Inadequate skin preparation. Poor electrode-skin contact. Diagnostic frequency response.	• Prepare skin and reapply electrodes. • Check electrodes for proper adhesion. • Print ECG in monitor frequency response.
5 Fine baseline artifact (high frequency/low amplitude).	Inadequate skin preparation. Isometric muscle tension in arms/legs.	• Prepare skin and reapply electrodes. • Confirm that limbs are resting on a supportive surface. • Check electrodes for proper adhesion.
6 Systole beeps not heard or do not occur with each QRS complex.	Volume too low. QRS amplitude too small to detect.	• Adjust volume. • Change ECG lead.
7 Monitor displays dashed lines with no ECG leads off messages.	Paddles lead selected but patient connected to ECG cable.	• Select one of the limb leads.
8 Heart rate (HR) display different than pulse rate.	Monitor is detecting the patient's internal pacemaker pulses.	• Change ECG lead. • Change monitor lead to reduce internal pacemaker pulse size.
9 Internal pacemaker pulses difficult to see.	Pulses from pacemaker are very small. Monitor the visibility of frequency response limits.	• Turn on internal pacemaker detector (refer to page 2-8). • Connect ECG cable and select ECG lead instead of paddles. • Print ECG in diagnostic mode (refer to page 2-8).

MONITORING SpO2

The following paragraphs describe:

- SpO2 Warnings and Cautions
- When to Use a Pulse Oximeter
- How a Pulse Oximeter Works
- SpO2 Monitoring Considerations
- SpO2 Monitoring Procedure
- Pulse Oximeter Sensors
- SpO2 Volume
- Troubleshooting Tips for SpO2

SpO2 Warnings and Cautions

Before use, carefully read the sensor and extension cable directions for use and precautionary information.

WARNINGS!

Shock or burn hazard.

Other manufacturers' oxygen transducers may cause improper oximeter performance and invalidate safety agency certification. Use only oxygen transducers approved for this product.

WARNINGS!

Inaccurate pulse oximeter readings.

Do not use a damaged extension cable or one with exposed electrical contacts. Never use more than one extension cable between the pulse oximeter and the sensor.

Inaccurate pulse oximeter readings.

Sensors exposed to ambient light when incorrectly applied to a patient may exhibit inaccurate saturation readings. Securely place the sensor on the patient and check the sensor's application frequently to help ensure accurate readings.

Inaccurate pulse oximeter readings.

Significant blood levels of carboxyhemoglobin or methemoglobin, excessive patient movement, venous pulsations, electrosurgical interference, and placement of the sensor on an extremity that has a blood pressure cuff or intravascular line may interfere with oximeter performance. The operator should be thoroughly familiar with the operation of the oximeter prior to use.

Skin injury.

Prolonged, continuous use of a sensor may cause irritation, blistering, or pressure necrosis of the skin. Check the sensor site regularly based on patient condition. Change the sensor site if skin changes occur. Do not use tape to hold the sensor in place.

CAUTION!

Possible equipment damage.

To avoid damaging the extension cable or the sensor, hold the connectors, rather than the cables, when disconnecting.

When to Use a Pulse Oximeter

A pulse oximeter is a noninvasive device that checks the saturation of oxygen in arterial blood (SpO2). It is used for monitoring patients who are at risk of developing hypoxemia. If a pulse oximeter is not used, the only indications of hypoxemia are a patient's dusky skin, nail beds, and mucous membranes, accompanied by restlessness and confusion. These indications are not conclusive, however, and do not appear until after the patient has developed hypoxemia. Pulse oximetry is a tool to be used in addition to patient assessment. Care should be taken to assess the patient at all times and not to rely solely on the SpO2 reading. If a trend toward patient deoxygenation is indicated, blood samples should be analyzed using laboratory instruments to completely understand the patient's condition.

How a Pulse Oximeter Works

A pulse oximeter sensor directs light through a fleshy body site (usually the finger or earlobe). The sensor sends light from the emitting diodes to the receiving detector as shown in Figure 3-4. Oxygen saturated blood absorbs light differently as compared to unsaturated blood. The pulse oximeter translates the amount of light received into a saturation percentage and displays an SpO2 reading. Normal values typically range from 95% to 100% at sea level.

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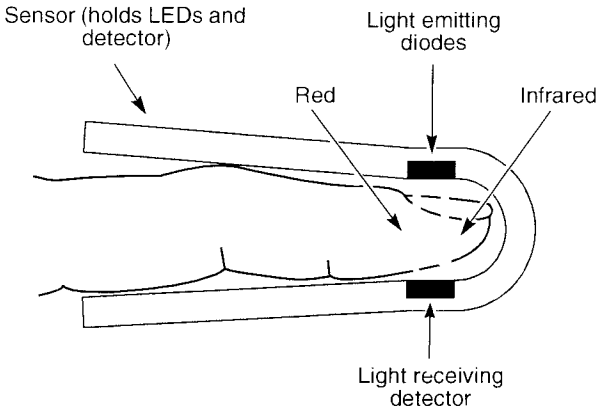


Figure 3-4 How a Pulse Oximeter Works

The quality of the SpO2 reading depends on correct sensor size and placement, adequate blood flow through the sensor site, patient motion, and exposure to ambient light. Test methods for accuracy are available by contacting your local Medtronic representative.

SpO2 Monitoring Considerations

Each oximeter sensor is applied to a specific site on the patient. Use the following criteria to select the appropriate sensor:

- Patient weight
- Patient perfusion to extremities
- Patient activity level
- Available application sites on the patient's body
- Sterility requirements
- Anticipated duration of monitoring

To help ensure optimal performance:

- Use a dry and appropriately sized sensor.
- Keep the sensor site at the same level as the patient's heart.
- Apply it according to the Directions for Use provided with the sensor.
- Observe all warnings and cautions noted in the sensor's Directions for Use.

The sensors are sensitive to light. If excessive ambient light is present, cover the sensor site with an opaque material to block the light. Failure to do so could result in inaccurate measurements.

If patient movements present a problem, consider the following possible solutions:

- Be sure the sensor is secure and properly aligned.
- Use a new sensor with fresh adhesive backing.
- If possible, move the sensor to a less active site.

SpO2 Monitoring Procedure

Power to the pulse oximeter is controlled by the defibrillator. When the defibrillator is turned on, the oximeter turns on and performs a self-test that requires up to 10 seconds. When the defibrillator is turned off, the oximeter also turns off.

To conserve battery power, the pulse oximeter goes into "sleep mode" when not in use. Sleep mode is activated within 10 seconds of disconnecting the sensor. The oximeter will return to normal mode after detecting a sensor or a patient signal. The oximeter performs the self-test when it returns from sleep mode to active mode. During sleep mode, the screen does not display SpO2 information.

The pulse oximeter measures SpO2 levels between 1% and 100%. When SpO2 levels are between 70% and 100%, oximeter measurements are accurate from ±3 digits.

1 Connect the SpO2 cable to the monitor.
2 Attach the sensor to the SpO2 cable and the patient.
3 Press ON.
4 Observe the pulse bar for fluctuation. Amplitude of the pulse bar indicates relative signal strength.
5 Adjust sensitivity, averaging time, and SpO2 volume as necessary.

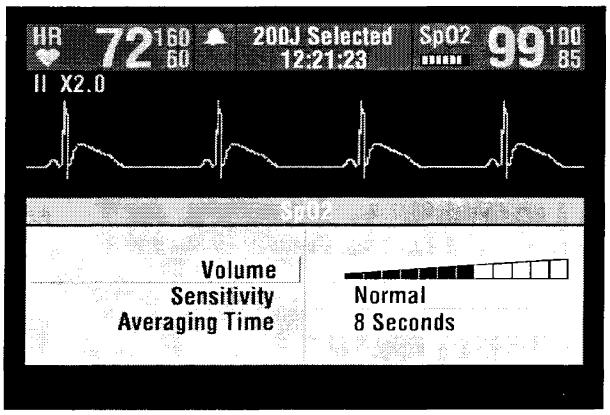
SpO2 Waveform

The SpO2 waveform can be displayed on waveform Channel 2 by selecting waveform Channel 2 and then selecting SpO2 from the Waveform menu. The SpO2 waveform automatically sizes itself to provide optimum waveform viewing.

SpO2 Volume

To adjust the pulse tone volume, highlight and select SPO2 on the home screen.

The following overlay appears:



1 Highlight and select SPO2 VOLUME.
2 Rotate the Speed Dial to the desired volume.
3 Press the Speed Dial to set the volume.

Sensitivity

The sensitivity setting allows you to adjust the oximeter for differing perfusion states. To adjust the sensitivity to either normal or high, highlight and select SPO2 on the home screen and then select SENSITIVITY.

The normal sensitivity setting is the recommended setting for most patients. The high sensitivity setting allows for Sp02 monitoring under low perfusion states such as the severe hypotension of shock. However, when the Sp02 sensitivity is set to high, the signal is more susceptible to artifact. It is recommended that the patient be monitored closely when the high sensitivity setting is in use.

Averaging Time

The averaging time setting allows you to adjust the time period used to average the Sp02 value. Four time periods are provided for averaging: 4, 8, 12, and 16 seconds. To adjust the averaging time, highlight and select SPO2 on the home screen and select AVERAGING TIME.

The averaging time of 8 seconds is recommended for most patients. For patients with rapidly changing SpO2 values, the 4-second time is recommended. The 12 and 16 second periods are used when artifact is affecting the performance of the pulse oximeter.

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Pulse Oximeter Sensors

Table 3-3 lists the sensors and extension cables to be used with the LIFEPAK 20 defibrillator/monitor. Carefully read the directions for use provided with these sensors for complete description, instructions, warnings, cautions, and specifications. To order sensors and extension cables, contact your local Medtronic representative.

Table 3-3 Sensors and Extension Cables

Description and Model Numbers	Patient Size
LNOP® Adt, 20/box, Medtronic	Single use sensor for patient >30 kg
LNOP Pdt, 20/box, Medtronic	Single use sensor for patient >10 kg <50 kg
LNOP Neo, 20/box, Medtronic	Single use sensor for neonates <10 kg
LNOP NeoPt, 20/box, Medtronic	Single use sensor for neonates <1 kg
LNOP DCI, 1/box, Medtronic	Reusable sensor for adults
LNOP DCIP, 1/box, Medtronic	Reusable sensor for pediatrics
PC04, 1/box, Medtronic	4' reusable connector cable
PC08, 1/box, Medtronic	8' reusable connector cable
PC12, 1/box, Medtronic	12' reusable connector cable

No Implied License

Possession or purchase of this oximeter does not convey any express or implied license to use the oximeter with replacement parts which would, alone or in combination with the oximeter, fall within the scope of one or more of the patents relating to this device.

Cleaning

To clean the sensor, first remove it from the patient and disconnect it from the connector cable. You may then clean the LNOP DCI by wiping it with a 70% isopropyl alcohol pad. Allow the sensor to dry before placing it on a patient.

Clean the connector cable by wiping it with a 70% isopropyl alcohol pad and allow it to dry. Do not soak or immerse the cable in any liquid solution. Do not attempt to sterilize.

Troubleshooting Tips for SpO2

Table 3-4 Troubleshooting Tips for SpO2

Observation	Possible Cause	Corrective Action
1 The oximeter measures a pulse, but there is no oxygen saturation or pulse rate.	Excessive patient motion.	• Keep patient still. • Check that sensor is secure. • Relocate sensor. • Replace sensor.
	Patient perfusion may be too low.	• Check patient. • Increase sensitivity.

Table 3-4 Troubleshooting Tips for SpO2 (Continued)

Observation	Possible Cause	Corrective Action
2 SpO2 or pulse rate changes rapidly; pulse amplitude is erratic.	Excessive patient motion.	• Keep patient still. • Check that sensor is secure. • Relocate sensor. • Replace sensor. • Increase sensitivity.
	An electrosurgical unit (ESU) may be interfering with performance.	• Move the monitor as far as possible from the ESU. • Plug the ESU and monitor into different circuits. • Move the ESU ground pad as close to the surgical site as possible. • Sensor may be damp, replace it. • Remove sensor extension cable and connect the sensor directly.
3 No SpO2 value is displayed.	Oximeter may be performing a self-test (requires 10 seconds).	• Wait for completion.
4 *SPO2: NO SENSOR DETECTED* message appears.	Sensor is not connected to patient or cable disconnects from device.	• Check that sensor and cable are connected properly.
5 *SPO2: CHK OK SENSOR* message appears.	Sensor is disconnected from patient or cable.	• Attach the sensor. • Check that sensor is secure.
	Excessive ambient light.	• Remove or block light source if possible. • Cover sensor with opaque material, if necessary.
	Patient has a weak pulse or low blood pressure.	• Test sensor on someone else. • Check if patient perfusion is adequate for sensor location. • Check if sensor is secure and not too tight. • Check that sensor is not on extremity with blood pressure cuff or intravascular line. • Change sensor location.
6 *SPO2: UNKNOWN SENSOR* message appears.	A sensor is connected to the device that is not a Medtronic approved sensor.	• Check that the sensor is an approved Medtronic sensor.
7 *SPO2: SEARCHING FOR PULSE* message appears.	A sensor is connected to the patient and is searching for a pulse.	• Wait for completion.
8 *SPO2: LOW PERFUSION* message appears.	Patient has a weak pulse.	• Change sensor location.

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THERAPY

This section describes patient therapy.

General Therapy Warnings and Cautions	page 4-2
Therapy Electrode and Standard Paddle Placement	4-3
Automated External Defibrillation	4-4
Manual Defibrillation	4-11
Pediatric Defibrillation	4-16
Noninvasive Pacing	4-19

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GENERAL THERAPY WARNINGS AND CAUTIONS

WARNINGS!

Shock hazard.

The defibrillator delivers up to 360 J of electrical energy. When discharging the defibrillator, do not touch the paddle electrode surfaces or disposable therapy electrodes.

Shock hazard.

If a person is touching the patient, bed, or any conductive material in contact with the patient during defibrillation, the delivered energy may be partially discharged through that person. Clear everyone away from contact with the patient, bed, and other conductive material before discharging the defibrillator.

Shock hazard.

Do not discharge the defibrillator into the open air. To remove an unwanted charge, change the energy selection, select disarm, or turn off the defibrillator.

Possible fire, burns, and ineffective energy delivery.

Do not discharge standard paddles on top of therapy electrodes or ECG electrodes. Do not allow standard paddles (or therapy electrodes) to touch each other, ECG electrodes, lead wires, dressings, transdermal patches, etc. Such contact can cause electrical arcing and patient skin burns during defibrillation and may divert defibrillating energy away from the heart muscle.

Possible defibrillator shutdown.

When operating on battery power, the large current draw required for defibrillator charging may cause the defibrillator to reach a shutdown voltage level with no low battery warning. If the defibrillator shuts down without warning, or if a *LOW BATTERY: CONNECT TO AC POWER* message appears on the monitor screen, immediately connect the ac power cord to an outlet.

Possible skin burns.

During defibrillation or pacing, air pockets between the skin and therapy electrodes may cause patient skin burns. Apply therapy electrodes so that entire electrode adheres to skin. Do not reposition the electrodes once applied. If the position must be changed, remove and replace with new electrodes.

Possible skin burns and ineffective energy delivery.

Therapy electrodes that are dried out or damaged may cause electrical arcing and patient skin burns during defibrillation. Do not use therapy electrodes that have been removed from foil package for more than 24 hours. Do not use electrodes beyond expiration date. Check that electrode adhesive is intact and undamaged. Replace therapy electrodes after 50 shocks.

Possible interference with implanted electrical device.

Defibrillation may cause implanted devices to malfunction. Place standard paddles or therapy electrodes away from implanted devices if possible. Check implanted device function after defibrillation.

CAUTION!

Possible equipment damage.

Prior to using this defibrillator, disconnect all equipment from the patient that is not defibrillator-protected.

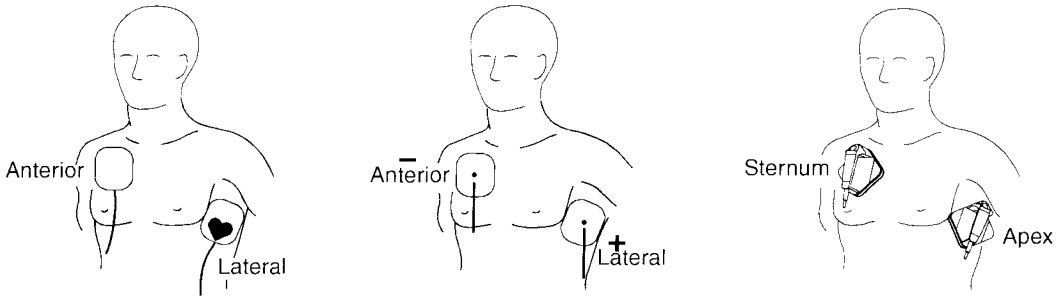
THERAPY ELECTRODE AND STANDARD PADDLE PLACEMENT

The following paragraphs describe therapy electrodes and standard paddles placement, including special placement situations.

Anterior-lateral Placement

Anterior-lateral placement allows for ECG monitoring, defibrillation, synchronized cardioversion, and noninvasive pacing.

1 Place either the ♥ or + therapy electrode, or apex paddle lateral to the patient's left nipple in the midaxillary line, with the center of the electrode in the midaxillary line, if possible. See Figure 4-1.



QUIK-COMBO Electrodes | **FAST-PATCH Electrodes** | **Standard Paddles**

Figure 4-1 Anterior-lateral Placement

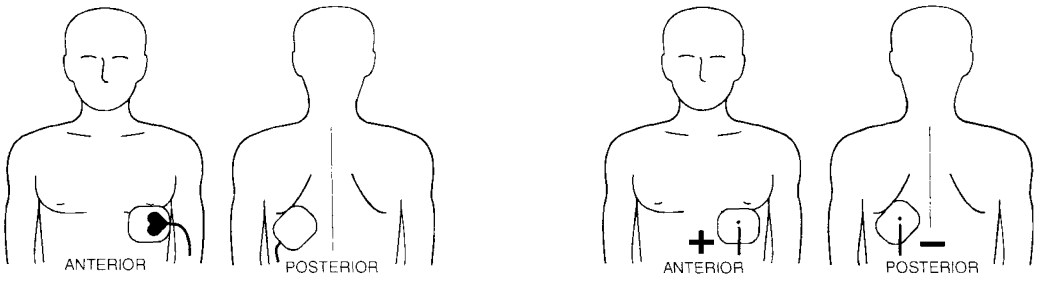
2 Place the other therapy electrode or sternum paddle on the patient's upper right torso, lateral to the sternum, and below the clavicle as shown in Figure 4-1.

Anterior-posterior Placement

Anterior-posterior is an alternative position for noninvasive pacing, manual defibrillation, and synchronized cardioversion, but not for ECG monitoring or automated defibrillation. The ECG signal obtained through electrodes in this position is not a standard lead.

1 Place either the ♥ or + therapy electrode over the left precordium as shown in Figure 4-2. The upper edge of the electrode should be below the nipple. Avoid placement over the nipple, the diaphragm, or the bony prominence of the sternum if possible.

2 Place the other electrode behind the heart in the infrascapular area as shown in Figure 4-2. For patient comfort, place the cable connection away from the spine. Do not place the electrode over the bony prominences of the spine or scapula.



QUIK-COMBO Electrodes | **FAST-PATCH Electrodes**

Figure 4-2 Anterior-posterior Placement for Noninvasive Pacing or Defibrillation

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Special Placement Situations

When placing therapy electrodes or standard paddles, be aware of the special requirements in the following possible situations.

Synchronized Cardioversion

Alternative anterior-posterior placements for cardioversion of supraventricular arrhythmias include:

- Place the ♥ or + therapy electrode over the left precordium and the other electrode on the patient's right posterior infrascapular area

  – or –

- Place the ♥ or + therapy electrode to the right of the sternum and the other electrode on the patient's posterior left infrascapular area.

If using standard paddles for anterior-posterior placement, use the posterior paddle (PN 802461) and refer to Section 5, Paddle Accessory Options.

Obese Patients or Patients with Large Breasts

Apply therapy electrodes or standard paddles to a flat area on the chest, if possible. If skin folds or breast tissue prevent good adhesion, it may be necessary to spread skin folds apart to create a flat surface.

Thin Patients

Follow the contour of the ribs and spaces when pressing the therapy electrodes onto the torso. This limits air spaces or gaps under the electrodes and promotes good skin contact.

Patients with Implanted Pacemakers

If possible, place therapy electrodes or standard paddles away from the internal pacemaker generator to help prevent damage to the pacemaker. Treat the patient like any other patient requiring care. When operating the defibrillator in AED mode, pacemaker pulses may prevent advisement of an appropriate shock, regardless of the patient's underlying rhythm.

Patients with Implanted Defibrillators

Apply therapy electrodes or standard paddles in the anterior-lateral position and treat this patient as any other patient requiring emergency care. If defibrillation is unsuccessful, it may be necessary to try alternate electrode placement (anterior-posterior) due to the insulative properties of implanted defibrillator electrodes.

AUTOMATED EXTERNAL DEFIBRILLATION

The following paragraphs include:

AED Warnings
AED Configuration
AED Procedure
Troubleshooting Tips for AED Mode

AED Warnings

WARNINGS!

Possible misinterpretation of data.

Do not analyze while patient is moving or being transported. Motion artifact may affect the ECG signal resulting in an inappropriate shock or no shock advised message. Motion detection may delay analysis. Stop motion and stand clear of patient during analysis.

Pediatric patient safety risk.

In AED mode, this defibrillator is not designed to administer energy at pediatric joule settings. The American Heart Association recommends AEDs be used only on patients who are more than eight years old.

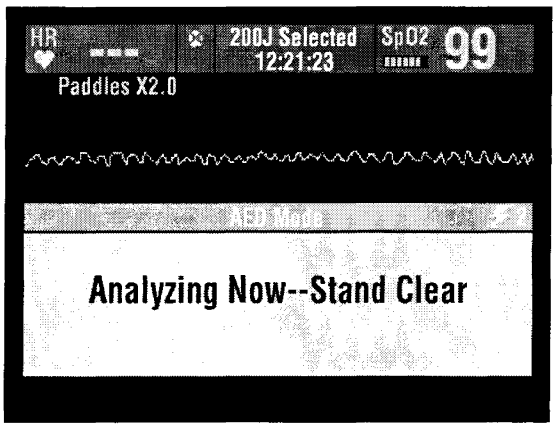
AED Configuration

You can configure the LIFEPAK 20 defibrillator/monitor to turn on in AED mode before placing the device in use (refer to Section 8).

When illuminated, the AED mode LED indicates that the Continuous Patient Surveillance System (CPSS) is active. CPSS automatically monitors the patient ECG for a potentially shockable rhythm.

When the ANALYZE button is pressed, the Shock Advisory System (SAS) is active. SAS is an ECG analysis system that advises the user if it detects a shockable or nonshockable rhythm.

The LIFEPAK 20 defibrillator/monitor can be configured to display the ECG waveform in AED mode or to not display a waveform. The operation in AED mode remains the same whether or not the ECG waveform is displayed.



When the ECG waveform is set to ON in the setup configuration (refer to Section 8), the ECG appears with all of the AED messages and prompts, as shown in the screen to the left.

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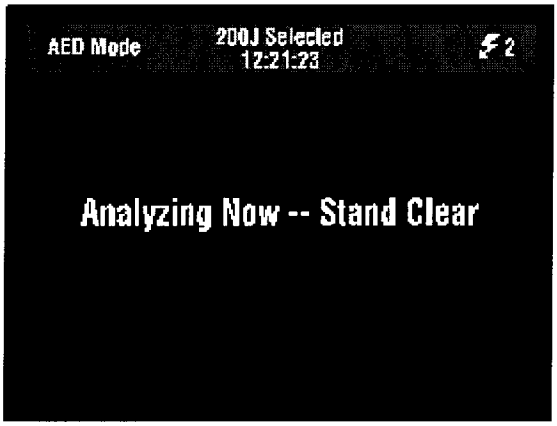
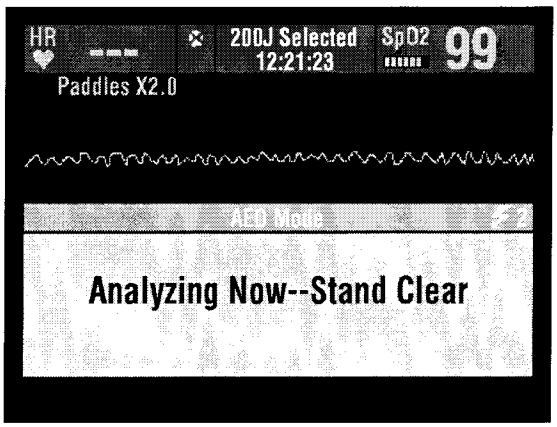


When the ECG waveform is set to OFF in the setup configuration, the messages and prompts fill the screen as shown in the screen to the left.

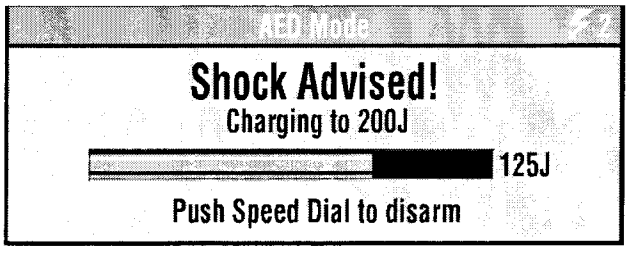
AED Procedure

1 Verify that the patient is in cardiac arrest (unconscious, no respiration, no pulse).
2 Press ON.
3 Prepare the patient for electrode placement (refer to Paddles Monitoring Procedure, page 3-4). The *CONNECT ELECTRODES* message and voice prompt occur until the patient is connected to the AED.
4 Apply the electrodes to the patient's chest in the anterior-lateral position (refer to Anterior-lateral Placement, page 4-3).
5 Press ANALYZE to initiate analysis. Stop CPR.
6 Follow screen messages and voice prompts provided by the AED.

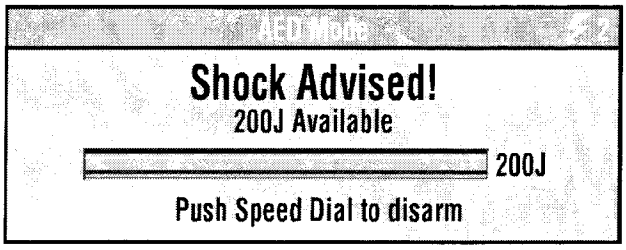


You will see and hear *ANALYZING NOW, STAND CLEAR*. Do not touch or move the patient or therapy cable during analysis. ECG analysis requires approximately 6 to 9 seconds. The analyze LED illuminates during analysis.

Shock Advised



If the AED detects a shockable ECG rhythm, you will see and hear *SHOCK ADVISED*. The AED begins charging to the configured joule setting for shock #1. A rising tone indicates that the AED is charging.



When charging is complete, the AED displays the available energy.

You will see and hear *STAND CLEAR. PUSH TO SHOCK* (⚡) followed by a "shock ready" tone. The shock LED flashes. Clear everyone away from the patient, bed, or any equipment connected to the patient.

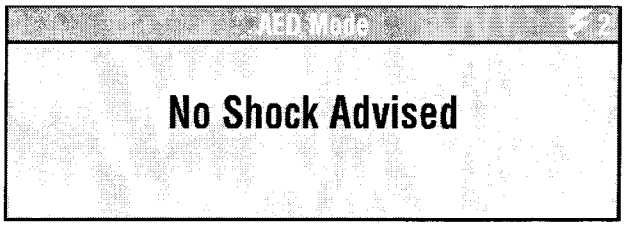
Press the ⚡ button to discharge the AED.

If you do not press ⚡ within 60 seconds, the AED disarms the shock button, and the *DISARMING* message appears.

If auto analyze is on, the AED automatically analyzes the patient's ECG rhythm after shock #1 is delivered. If auto analyze is off, the *PUSH ANALYZE* message and voice prompt occur. You must press ANALYZE to begin the analysis.

The second analysis and shock sequence is the same as described for shock #1. The energy level for Shock #2 depends on device configuration for energy protocol and the analysis decision. When a *NO SHOCK ADVISED* prompt follows a shock, the energy level will not increase for the next shock. For subsequent shocks, the highest energy level available is 360 J.

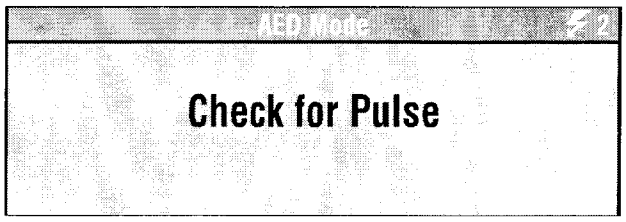
No Shock Advised



If the AED detects a nonshockable rhythm, you will see and hear *NO SHOCK ADVISED*. The AED will not charge, and a shock can not be delivered.

After *NO SHOCK ADVISED*, the AED enters CPR Time (if configured on).

CPR Time



After either a *NO SHOCK ADVISED* prompt or three consecutive shocks, you will see and hear *CHECK FOR PULSE*.

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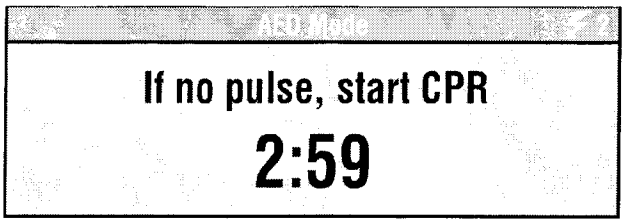
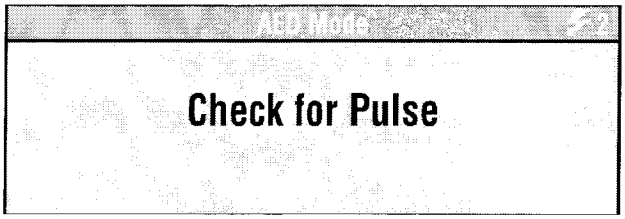


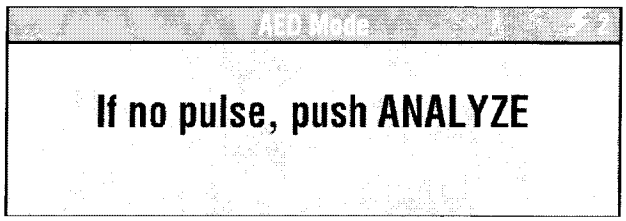
After 10 seconds, you will see and hear *IF NO PULSE, START CPR* if CPR Time is configured on.

If a pulse is present, proceed with your standard protocol. If no pulse, start CPR. A message and countdown timer (min:sec format) displays for the remaining CPR Time.

Note: You can press ANALYZE at any time to start an analysis cycle.



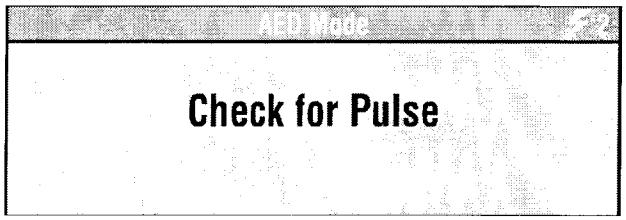
After CPR Time, you will see and hear *CHECK FOR PULSE.*



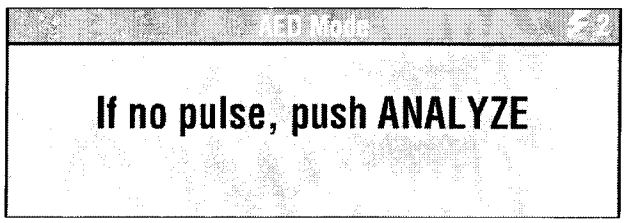
After 10 seconds, you will see and hear *IF NO PULSE, PUSH ANALYZE.*

If a pulse is present, proceed with your standard protocol. If not, press ANALYZE.

CPR Time Off



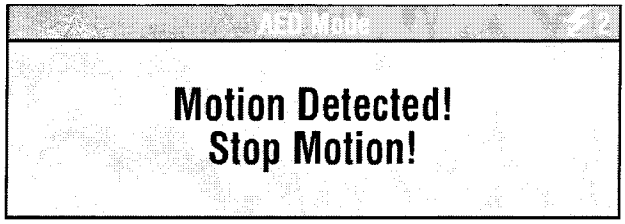
After a *NO SHOCK ADVISED* prompt or three consecutive shocks, you will see and hear *CHECK FOR PULSE.*



After 10 seconds, you will see and hear *IF NO PULSE, PUSH ANALYZE* if CPR Time is configured off.

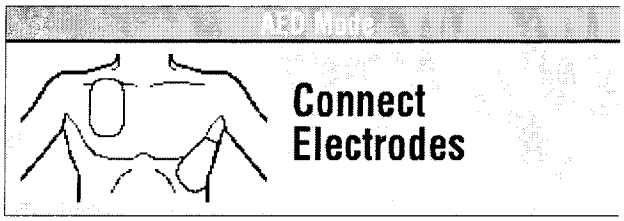
If a pulse is present, proceed with your standard protocol. If not, press ANALYZE.

Motion Detected

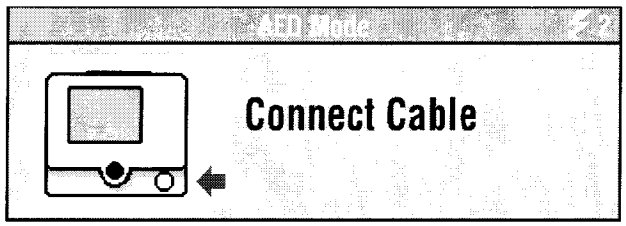


If the motion is detected during the ECG analysis, you will see and hear *MOTION DETECTED, STOP MOTION* followed by a warning tone. If the motion ceases within 20 seconds, analysis will continue. If the motion does not cease within 20 seconds, analysis will stop. You must then press ANALYZE to restart analysis. Refer to Table 4-1, page 4-10 for possible causes and suggested solutions.

Electrodes Off



If therapy electrodes are not connected, the *CONNECT ELECTRODES* message and voice prompt occur until the patient is connected to the AED.

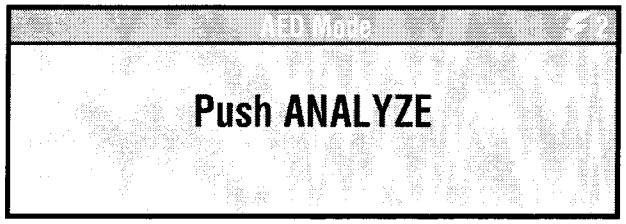


If the therapy cable is not connected to the defibrillator, you will see the *CONNECT CABLE* message until the cable is connected.

Shock Counter

The shock counter (x) indicates how many shocks have been delivered to the patient. The shock counter resets to zero whenever the defibrillator is turned off.

Continuous Patient Surveillance System (CPSS)



When the AED is not analyzing the ECG or is in CPR Time, it continuously monitors the ECG for a potentially shockable rhythm (CPSS).

If the AED detects a shockable rhythm, you will see and hear *PUSH ANALYZE*.

You should:

1 Confirm the patient is unconscious, pulseless, and not breathing normally.
2 Confirm no motion is present. Stop CPR.
3 Press ANALYZE.
   The AED begins to analyze the patient's ECG.

For information about changing the defibrillation mode, refer to Section 8.

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Troubleshooting Tips for AED Mode

Table 4-1 Troubleshooting Tips for AED Mode

Observation	Possible Cause	Corrective Action
1 *CONNECT ELECTRODES* message appears.	Inadequate connection to defibrillator.	• Check for electrode connection.
	Electrodes do not adhere properly to the patient.	• Press electrodes firmly on patient's skin. • Clean, shave, and dry the patient's skin as recommended.
	Electrodes are dry, damaged, or out of date.	• Replace the electrodes.
2 *MOTION DETECTED* and *STOP MOTION* messages appear during analysis.	Patient movement.	• Stop CPR during analysis. • When patient is being manually ventilated, press ANALYZE after complete exhalation. • Move patient to stable location when possible.
	Patient movement because of agonal respirations.	• Press ANALYZE immediately after exhalation or wait until agonal respirations are slower or absent.
	Electrical/radio frequency interference.	• Move hand-held communication devices or other suspected devices away from the defibrillator when possible.
3 *DISARMING* message appears.	Electrode disconnected from patient or AED.	• Replace electrode and press ANALYZE.
	Shock button not pressed within 60 seconds or door is open.	• Press ANALYZE again. • Press SHOCK immediately when directed.
4 Voice prompts sound faint or distorted.	Low battery power.	• Connect to ac power.
5 *LOW IMPEDANCE-RECHARGING* message appears.	Patient impedance <15 ohms detected.	• No action required.

Switching from AED to Manual Mode

f the front console door is closed, you can enter manual mode by pressing the MANUAL button located n the lower left corner of the door. This opens the door and automatically takes the defibrillator out of AED mode, allowing you to access manual mode defibrillation and pacing.

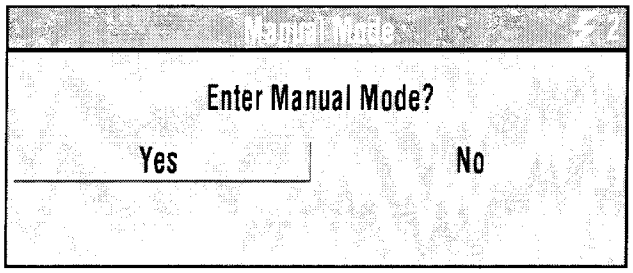
lote: Closing the door again will not return the device to AED mode. Pressing ANALYZE while the levice is in manual mode will place the defibrillator in AED mode.

f the door is not installed, press one of the following: ENERGY SELECT, CHARGE, PACER, LEAD SELECT.

)epending on the defibrillator's configuration, continue to manual mode as follows:

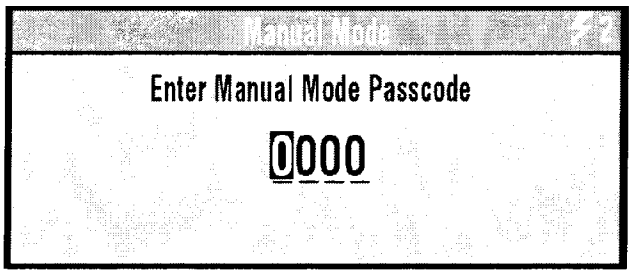
Direct. No restrictions to manual mode access is immediate.

- **Confirm**. A confirmation overlay appears:



Select YES to change to manual mode.

- **Passcode**. A passcode overlay appears:



Enter the passcode to change to manual mode.

Refer to Section 8 for information about changing the defibrillation mode.

MANUAL DEFIBRILLATION

The following paragraphs describe:

- Manual Defibrillation Warnings
- Impedance
- Defibrillation Shock Overlays
- Defibrillation Procedure
- Synchronized Cardioversion Procedure
- Remote Synchronization Procedure

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Manual Defibrillation Warnings

WARNINGS!

Possible fire, burns, and ineffective energy delivery.

Precordial lead electrodes and lead wires may interfere with the placement of standard paddles or therapy electrodes. Before defibrillation, remove any interfering precordial lead electrodes and lead wires.

Shock hazard.

Conductive gel (wet or dry) on the paddle handles can allow the electrical energy to discharge through the operator during defibrillation. Completely clean the paddle electrode surfaces, handles, and storage area after defibrillation.

Possible patient skin burns.

During defibrillation, air pockets between the skin and standard paddles can cause patient skin burns. Completely cover paddle electrode surfaces with fresh conductive gel and apply 11.3 kg (25lbs.) of pressure per paddle during discharge.

Possible paddle damage and patient skin burns.

Discharging the defibrillator with the standard paddle surfaces shorted together can pit or damage the paddle electrode surface. Pitted or damaged paddle surfaces may cause patient skin burns during defibrillation. Discharge the defibrillator only as described in these Operating Instructions.

Possible burns and ineffective energy delivery.

A gel pathway on the skin between the standard paddles will cause defibrillating energy to arc between paddles and divert energy away from the heart muscle. Do not allow conductive gel (wet or dry) to become continuous between paddle sites.

Possible damage to defibrillator and defibrillator shutdown.

When used in conjunction with another defibrillator to deliver more than 360J, one or both defibrillators may be damaged and shutdown may occur due to excessive currents. Avoid simultaneous discharge from both defibrillators and maintain a backup device in case one or both defibrillators shut down. If the defibrillator shuts down, take the device out of service and contact a qualified service technician.

To use the LIFEPAK 20 defibrillator/monitor primarily as a manual defibrillator, configure the defibrillator before placing the device in use. To configure the defibrillator, refer to Section 8.

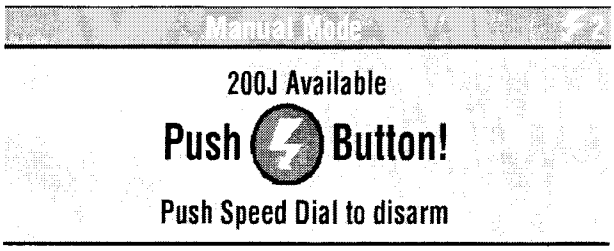
mpedance

.IFEPAK biphasic defibrillators measure the patient's transthoracic impedance and automatically adjust he defibrillation waveform current duration and voltage to meet the needs of the individual patient. 'atient impedance is measured whenever defibrillation electrodes or Standard Paddles are in contact vith the patient.

Defibrillation Shock Overlays

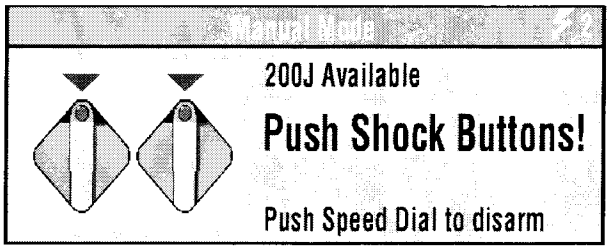
Depending on the paddles accessory connected to the defibrillator, you will see the following overlays when the defibrillator is fully charged.

QUIK-COMBO or FAST-PATCH Electrodes



Press SHOCK on the front panel to discharge energy.

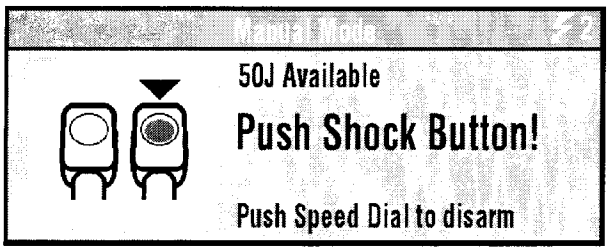
Standard Paddles



Press both SHOCK buttons simultaneously to discharge energy.

The front panel SHOCK button is disabled.

Internal Handles with Discharge Control



Press the SHOCK button on the internal handle to discharge energy.

The front panel SHOCK button is disabled.

Defibrillation Procedure

You can configure the LIFEPAK 20 defibrillator/monitor to automatically sequence energy levels. Refer to Manual Mode Setup Menu, page 8-4.

1 Press ON.

2 Identify the electrode or paddle sites on the patient. Use either the anterior-lateral or anterior-posterior position as described on page 4-3.

3 Prepare the patient's skin for electrode application:

- If possible, place the patient on a firm surface away from standing water or conductive material.
- Remove clothing from the patient's upper torso.
- Remove excessive hair from the electrode sites; if shaving is necessary, avoid cutting the skin.
- Clean the skin and dry it briskly with a towel or gauze.
- Do not apply alcohol, tincture of benzoin, or antiperspirant to the skin.

4 Connect the therapy electrodes to the therapy cable, and confirm cable connection to the device.

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5 Apply therapy electrodes to the patient in anterior-lateral or anterior-posterior position. If using standard paddles, apply conductive gel to the paddles and place paddles on the patient's chest.

6 Press ENERGY SELECT or rotate the energy select dial on standard paddles.

7 Press CHARGE. While the defibrillator is charging, a charging bar appears and a ramping tone sounds, indicating the charging energy level. When the defibrillator is fully charged, an overlay appears (see Defibrillation Shock Overlays, page 4-13).

8 Make certain all personnel, including the operator, stand clear of the patient, bed, and any equipment connected to the patient.

9 Confirm ECG rhythms and available energy.

10 Press the SHOCK button(s) to discharge energy to the patient or press the Speed Dial to remove the charge. If the SHOCK button(s) are not pressed within 60 seconds, stored energy is internally removed.

Note: If you change the energy selection after charging has started, the energy is removed. Press CHARGE to restart charging.

11 Observe the patient and the ECG rhythm. If an additional shock is necessary, repeat the procedure beginning at Step 6.

Note: If the *ABNORMAL ENERGY DELIVERY* message appears and the shock is not effective, increase energy, if necessary, and repeat shock. (Also refer to page 4-18.)

For more information about defibrillation, refer to the booklet, *Defibrillation: What You Should Know.*

Synchronized Cardioversion Procedure

Note: The LIFEPAK 20 defibrillator/monitor can be configured to remain in synchronous mode or to return to asynchronous mode after discharge. It is important that you know how your defibrillator is configured. Refer to Manual Mode Setup Menu, page 8-4.

1 Press ON.

2 Attach patient ECG cable and ECG electrodes as described previously on page 3-5.

3 Select lead II or the lead with greatest QRS complex amplitude (positive or negative).

Note: To monitor the ECG through therapy electrodes, place the electrodes in the anterior-lateral position and select paddles lead.

WARNING!

Possible lethal arrhythmia.

Ventricular fibrillation may be induced with improper synchronization. DO NOT use the ECG from another monitor (slaving) to synchronize the LIFEPAK 20 defibrillator/monitor discharge. Always monitor the patient's ECG directly through the ECG cable, therapy cable or use the remote synchronization procedure. Confirm proper placement of the sense markers on the ECG.

4 Press SYNC. Confirm the sync LED blinks with each detected QRS complex.

Note: Press SYNC again to deactivate synchronous mode.

5 Observe the ECG rhythm. Confirm that a triangle sense marker appears near the middle of each QRS complex. If the sense markers do not appear or are displayed in the wrong locations (for example, on the T-wave), select another lead. (It is normal for the sense marker location to vary slightly on each QRS complex.)

Prepare the patient's skin for therapy electrode application as described in Step 3 of Defibrillation Procedure, page 4-13.

Connect the therapy electrodes to the therapy cable, and confirm cable connection to the device.

Apply therapy electrodes to the patient in the anterior-lateral or anterior-posterior position. If using standard paddles, apply conductive gel to the paddles and place paddles on the patient's chest.

Press ENERGY SELECT or rotate the energy select dial on the standard paddles.

10 Press CHARGE.

11 Make certain all personnel, including operator, stand clear of the patient, bed, and any equipment connected to the patient.

12 Confirm ECG rhythm. Confirm available energy.

13 Press and **hold** SHOCK button(s) until discharge occurs with next detected QRS complex and then release SHOCK button(s). If SHOCK buttons are not pressed within 60 seconds, stored energy is internally removed.

Note: If you change the energy selection after charging has started, the energy is removed internally. Press CHARGE to restart charging.

14 Observe patient and ECG rhythm. Repeat procedure from Step 4, if necessary.

Remote Synchronization Procedure

WARNINGS!

Possible lethal arrhythmia.

Ventricular fibrillation may be induced with improper synchronization. The hospital's biomedical engineering staff should perform synchronization delay measurements on the system, as a whole, to ensure that the 60 ms limit for synchronization delay is not exceeded, per requirements as specified in AAMI DF2. Always confirm proper placement of the sense markers on the ECG.

Possible monitor incompatibility

If the R-wave synchronization markers do not appear to be nearly simultaneous with the R-waves on the remote monitor display or are not present, do not proceed with synchronized cardioversion.

The LIFEPAK 20 defibrillator/monitor can be configured to receive an ECG source from a remote monitor (such as a bedside ECG monitoring system) by means of the ECG/SYNC connector on the back of the defibrillator/monitor. See Manual Mode Setup Menu, page 8-4. The remote monitor must have a sync out connector and a cable must be provided to make this connection. Refer to the LIFEPAK 20 Defibrillator/Monitor Service Manual for more details.

Note: The LIFEPAK 20 defibrillator/monitor can be configured to remain in synchronous mode or to return to asynchronous mode after discharge. It is important that you know how your defibrillator is configured. Refer to Manual Mode Setup Menu, page 8-4.

To perform the synchronized cardioversion using a remote monitoring ECG source:

Ensure defibrillator/monitor is connected to ac power.

Connect the sync cable to the defibrillator/monitor system connector and the remote monitor.

Press ON.

Attach the ECG cable from the remote monitor to the patient.

Press SYNC on the defibrillator/monitor.

Select REMOTE SYNC from the menu.

Note: The screen on the defibrillator/monitor will display the message *REMOTE SYNC* in place of any waveforms.

Observe the ECG rhythm on the remote monitor. Confirm that a sense marker appears above each QRS complex.

Confirm that the sync LED on the defibrillator/monitor blinks with each detected QRS on the remote monitor.

Follow steps 6 through 14 from Synchronized Cardioversion Procedure provided previously.

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PEDIATRIC DEFIBRILLATION

Pediatric paddles are part of the standard paddle set (refer to page 5-6).

Pediatric Paddle Placement

Pediatric paddles should be used for patients weighing less than 10 kg (22 lb) or for patients whose chest size cannot accommodate the adult therapy electrodes.

Adult paddles are recommended if the paddles will fit completely on the patient's chest. Allow at least 2.5 cm (1 in.) of space between the paddles.

For neonates with very small chests, pediatric paddles may be too large to place in the anterior-lateral position. In this situation, place paddles in the anterior-posterior position. Holding the paddles against the chest and back will support the patient on his/her side.

Do not use the pediatric paddles on adults or older children. Delivery of recommended adult energies through this relatively small electrode surface increases the possibility of skin burns.

Anterior-Lateral

The following is the standard pediatric paddle placement (see Figure 4-3):

- Sternum paddle to the patient's right upper torso, lateral to the sternum and below the clavicle.
- Apex paddle lateral to the patient's left nipple in the midaxillary line, with the center of the paddle in the midaxillary line if possible.

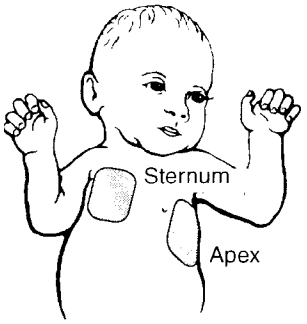

Figure 4-3 Anterior-lateral Paddle Position

Anterior-Posterior

Place the sternum paddle anteriorly over the left precordium and the apex paddle posteriorly behind the heart in the infrascapular area (see Figure 4-4).

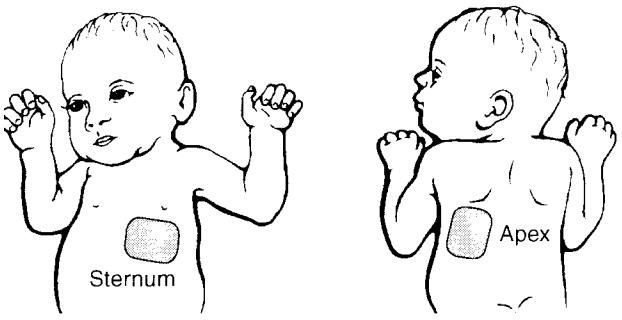

Figure 4-4 Anterior-posterior Paddle Position

Defibrillation Procedure

To defibrillate the patient:

1 Press ON to turn on the defibrillator.
2 To access the pediatric paddles, slide the adult paddle forward until it releases.
3 Apply defibrillation gel to the pediatric paddle electrode surfaces.
4 Select the appropriate energy for the weight of the child according to American Heart Association recommendations (or equivalent guidelines).
5 Place the paddles firmly on the patient's chest.
6 Press CHARGE.
7 Make certain all personnel, including the operator, are clear of the patient, the bed, and any equipment connected to the patient.
8 Confirm ECG rhythm and available energy.
9 Press the SHOCK button(s) to discharge energy to the patient or press the Speed Dial to remove the charge. If SHOCK buttons are not pressed within 60 seconds, stored energy is internally removed.

Note: If you change the energy selection after charging has started, the energy is removed. Press CHARGE to restart charging.

Note: If the *ABNORMAL ENERGY DELIVERY* message appears and the shock is not effective, increase energy, if necessary, and repeat shock. (Also refer to page 4-18.)

Troubleshooting Tips for Defibrillation and Synchronized Cardioversion

Table 4-2 Troubleshooting Tips for Defibrillation and Synchronized Cardioversion

Observation	Possible Cause	Corrective Action
1 Charge time to 360 J exceeds 10 seconds.	Battery low.	• Connect to ac power. • Device operating in low temperature environment (<25°C or 77°F).
2 Energy not delivered to patient when SHOCK button(s) are pressed.	Device in sync mode and QRS complexes are not detected.	• Change ECG lead for optimum sensing QRS or deactivate SYNC.
	Device in sync mode; shock button(s) not pressed and held until next detected QRS.	• Hold shock buttons until discharge occurs or next detected QRS.
	Shock button(s) pressed before full charge reached.	• Wait for tone and message indicating full charge.
	Sixty seconds elapsed before shock button(s) pressed after full charge. Energy internally removed.	• Press Shock button(s) within 60 seconds of full charge.
	ENERGY selection changed.	• Press CHARGE again.
3 *CONNECT CABLE* or *ENERGY NOT DELIVERED* message appears.	Therapy cable became disconnected and energy was removed internally.	• Reconnect cable and press charge again.
4 *ENERGY FAULT* message appears (selected and available energy).	Defibrillator is out of calibration.	• May still transfer energy. • Contact qualified service personnel.

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Table 4-2 Troubleshooting Tips for Defibrillation and Synchronized Cardioversion (Continued)

Observation	Possible Cause	Corrective Action
5 *DISARMING* message appears.	Discharge button not pressed within 60 seconds after charge complete.	• Recharge the defibrillator if desired.
	Energy selected after charge complete.	• Recharge the defibrillator.
	Therapy cable disconnects.	• Reconnect electrode/cable.
6 Patient didn't jump (no muscle response) during defibrillator discharge.	Patient muscle response is variable and depends on patient condition. Lack of visible response to defibrillation does not necessarily mean the discharge did not occur.	• No action needed.
7 *ABNORMAL ENERGY DELIVERY* message appears and Shock XJ Abnormal annotated on printout.	Open air discharge with standard paddles.	• Press paddles firmly on patient's chest when discharging. • Perform test discharges with defibrillation checker.
	Discharge occurs with standard paddles shorted together.	• Refer to warning, page 4-12.
	Patient impedance out of range.	• Increase energy and/or repeat discharges as needed. • Consider replacing disposable therapy electrodes with new.
8 *CONNECT ELECTRODES* message appears.	Inadequate connection to defibrillator.	• Check for electrode connection.
	Electrodes do not adhere properly to the patient.	• Press electrodes firmly on patient's skin. • Clean, shave, and dry the patient's skin as recommended.
	Electrodes are dry, damaged, or out of date.	• Replace the electrodes.
9 *CONNECT TO AC POWER* message appears.	Remote sync is selected and the device is not connected to ac power.	• Connect to ac power. • Press SYNC to turn off remote sync.
10 *CONNECT SYNC CABLE TO REMOTE MONITOR* message appears.	Remote sync is selected and the device is not connected to the remote monitor.	• Connect to remote monitor. • Press SYNC to turn off remote synchronization.
11 *LOW IMPEDANCE RECHARGING* message appears.	Patient impedance of <15 ohms detected.	• No action required.
12 *SEARCHING FOR SIGNAL* message appears.	Remote sync is selected and the device is qualifying the input signal.	• No action required.

NONINVASIVE PACING

The LIFEPAK 20 defibrillator/monitor provides noninvasive pacing using QUIK-COMBO electrodes.

The following paragraphs include:

- Noninvasive Pacing Warnings
- Demand and Nondemand Pacing
- Noninvasive Pacing Procedure
- Troubleshooting Tips for Noninvasive Pacing

For information about noninvasive pediatric pacing, refer to Medtronic *Pediatric QUIK-COMBO pacing/defibrillation/ECG electrodes Operating Instructions* PN 3006260-001, included with each pediatric QUIK-COMBO electrode order.

Noninvasive Pacing Warnings

WARNINGS!

Possible interruption of therapy.

Observe the patient continuously while the pacemaker is in use. Patient response to pacing therapy, e.g., capture threshold, may change over time.

Possible inability to pace.

Using other manufacturers' combination therapy electrodes with this device could cause a decrease in pacing efficacy or the inability to pace because of unacceptably high impedance levels.

Possible patient skin burns.

Prolonged noninvasive pacing may cause patient skin irritation and burns, especially with higher pacing current levels. Discontinue noninvasive pacing if skin becomes burned and another method of pacing is available.

Demand and Nondemand Pacing

The noninvasive pacemaker can be used for either demand (synchronous) or nondemand (asynchronous) pacing modes.

The demand mode is used for most patients. In the demand mode, the LIFEPAK 20 defibrillator/monitor/pacemaker inhibits pacing when it senses the patient's own beats (intrinsic QRSs). In demand mode, if the ECG amplitude is too low to detect the patient's beats, or if an ECG lead becomes detached so that the ECG rhythm is not present, the pacemaker generates pacing pulses asynchronously. This means that the pacemaker generates pacing pulses at the selected rate, regardless of the patient's ECG rhythm.

Asynchronous or nondemand mode can be selected if noise or artifact interferes with proper sensing of QRS complexes. Press the OPTIONS button to access the nondemand mode. (Refer to page 2-7.)

The LIFEPAK 20 defibrillator/monitor has an integrated pulse oximeter that can be used in conjunction with a noninvasive pacemaker to help confirm capture. To confirm capture, compare the pulse rate measured by the oximeter to the set pacing rate of the pacemaker.

Noninvasive Pacing Procedure

ECG monitoring during pacing must be performed with the ECG electrodes and patient ECG cable. Pacing therapy electrodes cannot be used to monitor ECG rhythm and deliver pacing current at the same time. Be sure to place the therapy electrodes in the proper locations as described in the pacing procedure. Improper electrode placement may make a difference in the capture threshold.

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To pace, perform the following:

1 Press ON.

2 Connect the patient ECG cable, apply ECG electrodes to the ECG cable and patient, and select Lead I, II, or III. To receive the best monitoring signal, ensure there is adequate space between the ECG electrodes and the therapy electrodes.

3 Identify the QUIK-COMBO electrode sites on the patient. For pacing, use either the anterior-lateral or anterior-posterior position (refer to page 4-3).

4 Prepare patient's skin for electrode application as described in Step 3 of the Defibrillation Procedure.

5 Apply QUIK-COMBO electrodes to the patient.

6 Connect the therapy electrodes to the therapy cable.

7 Press PACER. Confirm the LED illuminates, indicating that the power is on.

8 Observe the ECG rhythm. Confirm that a triangle sense marker appears near the middle of each QRS complex. If the sense markers do not appear or are displayed in the wrong location (for example, on the T-wave), select another lead. (It is normal for the sense marker location to vary slightly on each QRS complex.)

9 Press RATE or rotate the Speed Dial to select the desired pacing rate.

Note: The RATE button changes the rate in 10 pulse per minute (ppm) increments; the Speed Dial changes the rate in 5 ppm increments.

10 Press CURRENT or rotate the Speed Dial to increase current until electrical capture occurs. For each delivered pacing stimulus, the PACER indicator flashes off and a positive pace marker displays on the ECG waveform.

11 Palpate the patient's pulse or check blood pressure and compare the SpO2 pulse rate with the set pacing rate to assess for mechanical capture. Consider use of sedation or analgesia if patient is uncomfortable.

Note: The CURRENT button changes the current in 10 mA increments; the Speed Dial changes the current in 5 mA increments.

Note: To change rate or current during pacing, press RATE or CURRENT, then rotate the Speed Dial.

Note: To interrupt pacing and view the patient's intrinsic rhythm, press and hold the PAUSE button. This causes the pacer to pace at 25% of the set rate. Release the PAUSE button to resume pacing at the set rate.

12 To stop pacing, reduce current to zero or press PACER.

Note: To defibrillate and stop noninvasive pacing, press ENERGY SELECT or charge the defibrillator. Pacing automatically stops. Proceed with defibrillation.

f the monitor detects ECG leads off during pacing, pacing continues at a fixed rate until the ECG lead is eattached. During fixed-rate pacing, the pacemaker delivers pulses at the set pace rate regardless of ıny intrinsic beats that the patient may have. The monitor continues to display the pacing rate (ppm) ınd the current (mA). To reestablish demand pacing, reattach the ECG lead.

Vhile pacing, visually monitor the patient at all times, *do not* rely on the *ECG LEADS OFF* warning to letect changes in pacing function. Routinely assess the ECG for proper sensing, pace pulse delivery, ılectrical capture, and mechanical capture.

f pacing electrodes detach during pacing, the *CONNECT ELECTRODES* and *PACING STOPPED* messages ıppear and an alarm sounds. The pacing rate is maintained and the current resets to 0 mA. Reattaching the pacing electrodes silences the alarm and removes the *CONNECT ELECTRODES* ıessage. The current remains at 0 mA until you increase the current manually.

Troubleshooting Tips for Noninvasive Pacing

Table 4-3 Troubleshooting Tips for Noninvasive Pacing

Observation	Possible Cause	Corrective Action
1 Device does not function when PACER is pressed.	Power off.	• Check if power is ON.
	Low battery.	• Connect to ac power.
2 PACER LED on, but CURRENT (MA) will not increase.	Therapy electrodes off.	• Check for message displayed. • Inspect therapy cable and electrode connections.
3 PACER LED on, CURRENT (MA) >0, but pace markers absent (not pacing).	Pacing rate set below patient's intrinsic rate.	• Increase PPM.
	Pacer oversensing (ECG artifact, ECG size too high).	• Establish clean ECG; decrease ECG size. • Select nondemand pacing.
4 Pacing stops spontaneously.	PACER button pressed off.	• Press PACER and increase the current.
	Internal error detected. Service message indicates an internal failure.	• Check for service indicator. • Cycle power and start pacing again. • Obtain service by qualified service personnel.
	Therapy electrode off.	• Check for message. Check pacing cable and electrode connections.
	ENERGY SELECT or CHARGE pressed.	• Press PACER and increase current. • Check for service message. • Cycle power and start pacing again.
	Radio frequency interference.	• Move radio equipment away from pacemaker.
5 Monitor screen displays distortion while pacing.	ECG electrodes not optimally placed with respect to pacing electrodes.	• Reposition electrodes away from pacing electrodes.
	Patient response to pacing is highly variable with respect to capture threshold and ECG distortion.	• Select another lead (I, II, or III). • Consider changing pacing rate.
6 Capture does not occur with pacing stimulus.	Current (mA) set too low.	• Increase pacing current. (Administer sedation/analgesia as needed.)
7 *CONNECT ELECTRODES* message appears.	Pacing cable or electrode disconnected.	• Reconnect and set current.
	Electrodes not adhering to skin.	• Prepare skin.
	Electrodes outdated.	• Replace electrodes and set current.
8 Pacing stops spontaneously and *PACER FAULT* message appears.	Internal error detected.	• Cycle power and start pacing again. • Obtain service by qualified service personnel.

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Table 4-3 Troubleshooting Tips for Noninvasive Pacing (Continued)

Observation	Possible Cause	Corrective Action
9 Intrinsic QRS complexes not sensed when pacing.	ECG amplitude too low to be sensed.	• Select another lead.
	Intrinsic QRS complexes are occurring during pacemaker's refractory period.	• Adjust PPM.
10 Pacing starts spontaneously.	Patient's heart rate falls below set pacing rate.	• Appropriate pacemaker function assess patient.
	During standby pacing, ECG lead disconnects.	• Reconnect ECG lead.
11 Set pacing rate (ppm) and ECG paced rate do not appear to match.	Internal error detected.	• Print ECG and calculate the pace rate.
12 Improper sensing (e.g., sensing on T-waves).	QRS complex too small. T-wave too large.	• Select another lead.

PADDLE ACCESSORY OPTIONS

Therapy Electrodes	page 5-2
Standard Paddle Set (Optional)	5-6
Posterior Defibrillation Paddle (PN 802461)	5-8
External Sterilizable Paddles (PN 3009166)	5-10
Internal Handles with Discharge Control (PN 3010901)	5-11
Cleaning and Sterilization Guidelines	5-14

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THERAPY ELECTRODES

The following paragraphs describe:

- About Therapy Electrodes
- Electrode Placement
- Cable Connection
- ECG Monitoring and Therapy Procedures
- Replacing and Removing Electrodes
- Testing

About Therapy Electrodes

There are two pre-gelled, self-adhesive therapy electrodes available: QUIK-COMBO pacing/ defibrillation/ECG electrodes and FAST-PATCH defibrillation/ECG electrodes (Figure 5-1). QUIK-COMBO electrodes are used for defibrillation, synchronized cardioversion, ECG monitoring, and pacing. FAST-PATCH electrodes can be used for defibrillation, synchronized cardioversion, and ECG monitoring, but not for pacing. To use FAST-PATCH electrodes with the LIFEPAK 20 defibrillator/monitor requires the addition of a FAST-PATCH defibrillation adapter cable (PN 3011030).

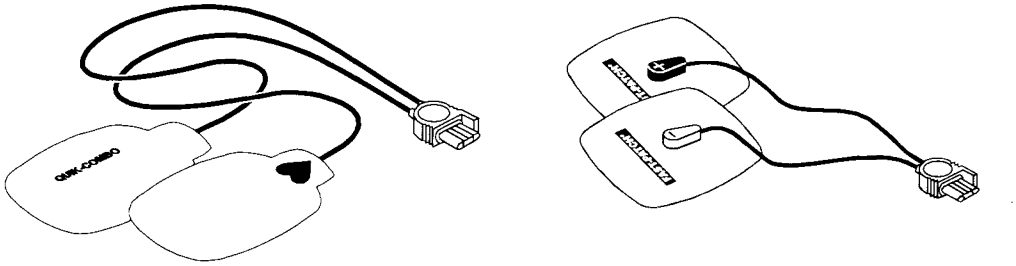

Figure 5-1 QUIK-COMBO and FAST-PATCH Electrodes

A QUIK-COMBO or FAST-PATCH electrode set:

Is a substitute for standard paddles.

Provides a Lead II monitoring signal when placed in the anterior-lateral position.

Quickly restores the ECG trace on the monitor following defibrillation.

To help prevent electrode damage:

Do not fold the electrodes.

Do not trim the electrodes.

Do not crush, fold, or store the electrodes under heavy objects.

Store electrodes in a cool, dry location (59° to 95°F or 15° to 35°C).

There are several types of QUIK-COMBO electrodes available as described in Table 5-1.

Table 5-1 QUIK-COMBO Electrodes

Type	Description
QUIK-COMBO	Electrodes, with .6 m (2 ft) of lead wire, designed for patients weighing 15 kg (33 lb) or more.
QUIK-COMBO - LLW	Electrodes, with 1 m (3.5 ft) of lead wire, designed for patients weighing 15 kg (33 lb) or more.
QUIK-COMBO - RTS	Electrodes, providing a radio-transparent electrode and lead wire set, designed for patients weighing 15 kg (33 lb) or more.
QUIK-COMBO with REDI-PAK™ preconnect system	Electrodes designed for patients weighing 15 kg (33 lb) or more and allow preconnection of the electrode set to the device while maintaining electrode shelf life and integrity.
Pediatric QUIK-COMBO	Electrodes designed for patients weighing 15 kg (33 lb) or less.

FAST-PATCH electrodes can be used on pediatric patients if the placement meets conditions noted in the following paragraphs. Usually, these conditions can be met by patients weighing 15 kg (33 lb) or more.

Electrode Placement

When using QUIK-COMBO or FAST-PATCH electrodes, ensure that the electrodes:

- Fit completely on the chest as described on page 3-4 or page 4-3.
- Have at least 2.5 cm (1 in.) of space between electrodes.
- Do not overlap bony prominences of sternum or spine.

To place the electrodes:

1. Prepare the patient for electrode placement:
   - Remove all clothing from the patient's chest.
   - Remove excessive chest hair as much as possible. Avoid nicking or cutting the skin if using a shaver or razor. If possible, avoid placing the electrodes over broken skin.
   - Clean and dry the skin. If there is ointment on the patient's chest, use soap and water to clean the skin. Briskly wipe the skin dry with a towel or gauze. This mildly abrades the skin and removes oils, dirt, and other debris for better electrode adhesion to the skin. Do not use alcohol, tincture of benzoin, or antiperspirant to prepare the skin.
2. Slowly peel back the protective liner on the electrodes, beginning with the cable connection end (see Figure 5-2).

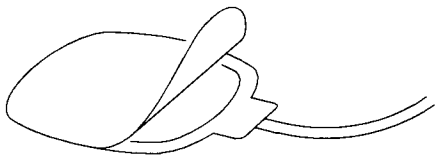

Figure 5-2 Peeling the Liner from the Electrode

3. Place the electrodes in the anterior-lateral or anterior-posterior position, as described on page 3-4 or page 4-3, depending on the therapy to be provided and special placement considerations.
4. Starting from one edge, firmly press the electrode on the patient's chest to eliminate air pockets between the gel surface and the skin. Firmly press all adhesive edges to the skin.

   Note: Once applied, therapy electrodes should not be repositioned.

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Cable Connection

To connect QUIK-COMBO electrodes to the QUIK-COMBO therapy cable:

1 Open the protective cover on the QUIK-COMBO therapy cable connector (see Figure 5-3).

2 Insert the QUIK-COMBO electrode connector into the therapy cable connector by aligning the arrows and pressing the connectors firmly together for proper attachment.

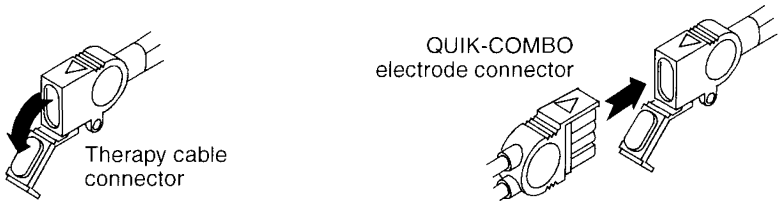

Figure 5-3 Connecting QUIK-COMBO Electrodes to Therapy Cable

To properly connect FAST-PATCH electrodes to the FAST-PATCH defibrillation adapter cable and ensure energy delivery:

1 Attach the defibrillation cable to the electrode post (before applying electrodes to the patient, when possible).

2 Support the electrode post when attaching the defibrillation cable (see Figure 5-4). Firmly press the cable onto the electrode until a click is heard or felt.

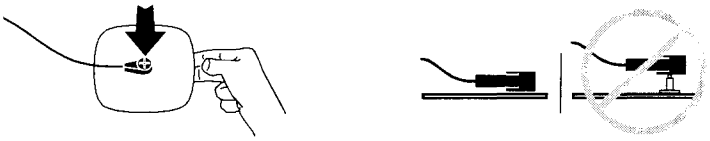

Figure 5-4 Connecting FAST-PATCH Electrodes to Defibrillation Cable

3 Pull up gently on the connector to confirm that the defibrillation cable is securely connected to the electrode.

Note: If you are reattaching the defibrillation cable to an electrode that is already on the patient, lift the adhesive edge under the electrode post slightly and place your finger under the post. Connect the cable as described in the preceding steps.

ECG Monitoring and Therapy Procedures

WARNINGS!

Possible patient skin burns.

Do not use Pediatric QUIK-COMBO electrodes on adults or larger children. Delivery of defibrillation energies equal to or greater than 100 J (typically used on adults) through these smaller electrodes increases the possibility of skin burns.

Possible pediatric patient skin burns.

Noninvasive pacing may cause patient skin irritation and burns, especially with higher pacing current levels. Inspect underlying skin of the ♥ electrode frequently after 30 minutes of continuous pacing. Discontinue noninvasive pacing if skin burn develops and another method of pacing is available. On cessation of pacing, immediately remove or replace electrodes with new ones.

For adult patients, follow the procedures for ECG monitoring, AED defibrillation, manual defibrillation, synchronized cardioversion, and pacing described in Section 3 or Section 4.

For pediatric patients, follow the procedures for ECG monitoring, manual defibrillation, synchronized cardioversion, and pacing except for the following:

- Select the appropriate defibrillation energy for the weight of the pediatric patient according to the American Heart Association (AHA) recommendations or local protocol. Using energy levels of 100 J or greater is likely to cause burns.
- When pacing, frequently inspect the patient's skin under the heart electrode for signs of burns.

Note: The amount of pacing current needed for capture is similar to the pacing current needed for adults.

Replacing and Removing Electrodes

Replace QUIK-COMBO or FAST-PATCH electrodes after 50 defibrillation shocks or 24 hours on the patient's skin. Replace QUIK-COMBO RTS electrodes after 8 hours of continuous pacing, pediatric QUIK-COMBO electrodes after 8 hours of continuous pacing, and all other QUIK-COMBO electrodes after 12 hours of continuous pacing.

To remove QUIK-COMBO or FAST-PATCH electrodes from the patient:

1 Slowly peel back the electrode from the edge, supporting the skin as shown in Figure 5-5.

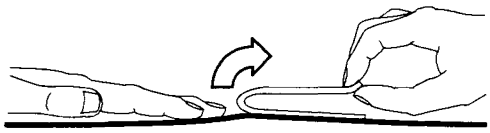

Figure 5-5 Removing Therapy Electrodes from Skin

2 Clean and dry the patient's skin.
3 When replacing electrodes, adjust the electrode positions slightly to help prevent skin burns.
4 Close the protective cover on the QUIK-COMBO therapy cable connector when the cable is not in use.

To disconnect the defibrillation cable from the FAST-PATCH electrodes:

1 Press down around the electrode post.
2 Pinch the snap connector with the fingers of the other hand and pull straight up (see Figure 5-6).

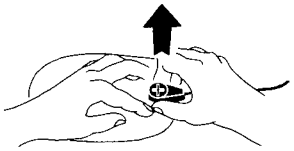

Figure 5-6 Disconnecting Defibrillation Cable from FAST-PATCH Electrodes

WARNING!

Possible cable damage and ineffective energy delivery or loss of monitoring.

Improper disconnection of the defibrillation cable may damage the cable wires. This can result in failure to deliver energy or loss of ECG signal during patient care. Position the cable so that it will not be pulled, snagged, or tripped over. Do not disconnect the defibrillation cable snap connectors from electrode posts or posts on testing devices by pulling on the cable. Disconnect the cable by pulling each cable connector straight out (see Figure 5-7).

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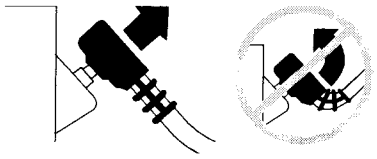


Figure 5-7 Disconnecting Defibrillation Cable from Test Post

Testing

As part or your defibrillator test routine, inspect and test the QUIK-COMBO therapy cable or FAST-PATCH defibrillation adapter cable. Daily inspection and testing will help ensure that the defibrillator and therapy cables are in good operating condition and are ready for use when needed. (Refer to Operator's Checklist, page D-1.)

If you detect any discrepancy during inspection and testing, remove the therapy cable from use and immediately notify a qualified service technician.

Cleaning and Sterilizing

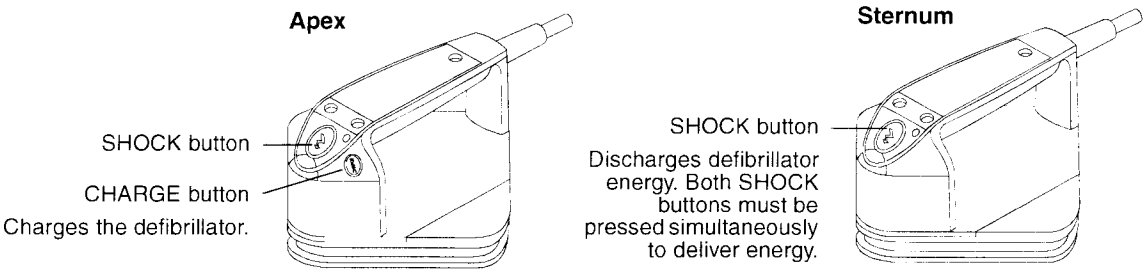
QUIK-COMBO and FAST-PATCH electrodes are not sterile or sterilizable. They are disposable and are to be used for a single patient application. Do not autoclave, gas sterilize, immerse in fluids, or clean electrodes with alcohol or solvents.

STANDARD PADDLE SET (OPTIONAL)

The following paragraphs describe:

- About the Standard Paddle Set
- Accessing the Pediatric Paddles
- Replacing the Adult Paddle Attachment
- Cleaning the Standard Paddle Set

Figure 5-8 illustrates the standard paddles' features.



igure 5-8 Standard Paddles

About the Standard Paddle Set

The standard paddle set consists of two parts:

- The handle assembly, which includes the pediatric paddle
- The adult paddle attachment

Features of the QUIK-LOOK defibrillation paddles can be used with both the pediatric paddle and adult paddle attachment.

Accessing the Pediatric Paddles

To access the pediatric paddles:

1 Grasp the standard paddle handle with one hand and the bottom of the adult paddle electrode with the other hand.
2 Slide the paddle handle back until you hear a click (see Figure 5-9).
3 Lift the paddle handle away from the adult attachment.
4 The pediatric paddle is now exposed and ready for use (see Figure 5-10).

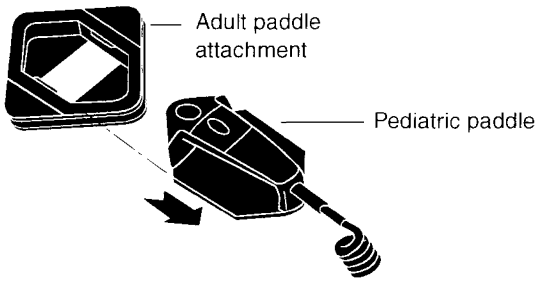


Figure 5-9 Accessing a Pediatric Paddle

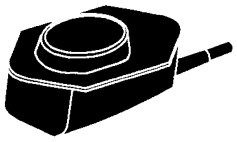


Figure 5-10 Pediatric Paddle (Bottom)

Replacing the Adult Paddle Attachment

To replace the adult paddle attachment:

1 Hold the adult paddle attachment with one hand and the standard handle with the other hand.
2 Fit the pediatric paddle onto the adult paddle attachment.
3 Slide the paddle handle forward until you hear a click. (See Figure 5-11.)

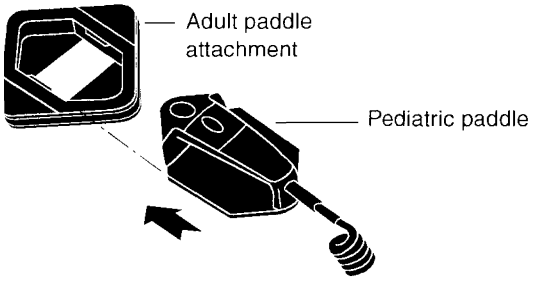


Figure 5-11 Replacing a Pediatric Paddle

Each adult paddle attachment has a contact spring plate that transfers energy from the pediatric paddle to the adult paddle. Routinely inspect the spring plates and pediatric paddle surfaces to make sure that they are clean and intact.

Cleaning the Standard Paddle Set

Individually protect paddles before and after cleaning to prevent damage to paddle surfaces. After each use:

Separate the adult and pediatric paddles.
Wipe or rinse paddle electrodes, cable connector, handles, and cables with mild soap and water or disinfectant using a damp sponge, towel, or brush. Do not immerse or soak.
Dry all parts thoroughly.
Examine paddles (including electrode surfaces), cables, and connectors for damage or signs of wear.

Note: Cables showing signs of wear, such as loose cable connections, exposed wires, or cable connector corrosion, should be removed from use immediately.

Note: Paddles with rough or pitted electrodes should be removed from use immediately.

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POSTERIOR DEFIBRILLATION PADDLE (PN 802461)

The following paragraphs describe:

- About the Posterior Defibrillation Paddle
- Installing the Paddle
- Removing the Paddle
- Paddle Placement
- Cleaning

Note: To use the posterior paddle, you must also use the LIFEPAK 12 defibrillator/monitor series standard paddle, PN 3006228. The posterior paddle will not fit on the LIFEPAK 20 defibrillator/monitor standard paddles set.

About the Posterior Defibrillation Paddle

The posterior defibrillation paddle slides onto a standard paddle when anterior-posterior placement is desired.

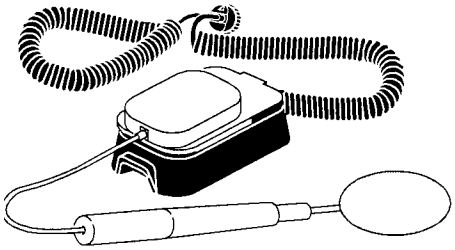


Figure 5-12 Posterior Defibrillation Paddle

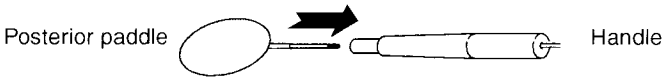
The posterior paddle attachment has a metal spring plate with a button on it to transfer defibrillation energy from the standard paddle electrode to the posterior paddle. This solid cadmium-silver button will not scratch the standard paddle electrode surface.

Note: Routinely inspect the spring plate and button to help ensure that they are clean and intact.

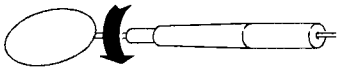
Installing the Posterior Paddle

To install the posterior paddle:

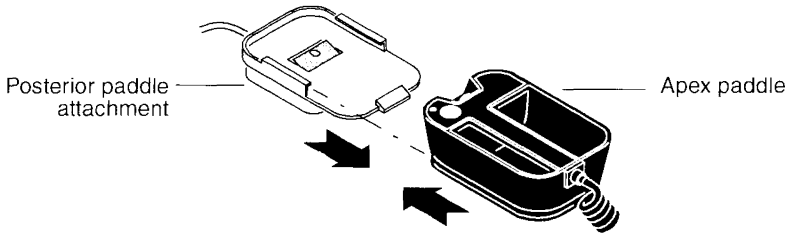
1. Insert the posterior paddle into the handle.



2. Turn clockwise until a positive stop is reached.



3 Slide the front end of the clean apex paddle onto the posterior paddle attachment. A click will be heard when fully engaged.



Note: Do not use conductive gel *between* the apex paddle and the posterior paddle attachment.

Removing the Posterior Paddle

To remove the posterior paddle:

1 Press down on the rear tab of the posterior paddle attachment (Figure 5-13, Arrow 1).

2 Slide the apex paddle off the paddle attachment (Figure 5-13, Arrow 2).

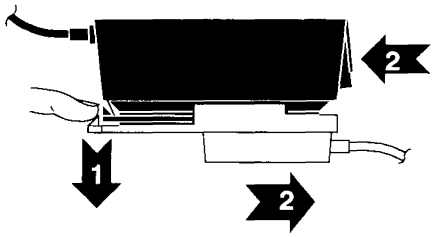
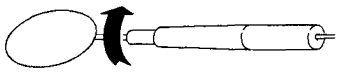
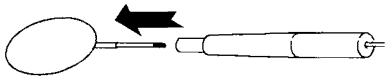


Figure 5-13 Removing the Paddle Attachment

3 Turn the posterior paddle counterclockwise until released from the handle.



4 Remove the paddle from the handle.



Paddle Placement

This accessory can only be used for anterior-posterior placement.

Anterior-Posterior

Place the sternum paddle anteriorly over the left precordium and the posterior paddle posteriorly behind the heart in the infrascapular area (see Figure 5-14).

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Follow procedures for manual defibrillation or synchronized cardioversion in Section 4.

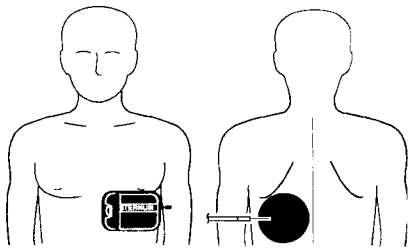


Figure 5-14 Anterior-posterior Paddle Position

Cleaning and Sterilizing

Protect the posterior paddle before and after cleaning to prevent damage to the paddle surface. After each use:

1 Remove posterior paddle from the handle.
2 Wipe or rinse paddle electrode, cable connector, paddle handle, and cable with mild soap and water or disinfectant using a damp sponge, towel, or brush. Do not immerse or soak.
3 Dry thoroughly.
4 Examine paddle electrode, cable connector, paddle handle, and cable for damage or signs of wear. Cables showing signs of wear such as loose cable connections, exposed wires, or cable connector corrosion should be removed from use immediately. A paddle with a rough or pitted electrode surface should be removed from use immediately.
5 Coil the cable loosely away from the paddle handle to sterilize. Wrapping the cable around the paddle handle may damage the cable.

The posterior paddle is approved for ethylene oxide gas or hydrogen peroxide plasma sterilization. The frequency of sterilization, rather than the age of the paddle, affects the useful life of the posterior defibrillation paddle. Refer to Cleaning and Sterilization Guidelines, page 5-14.

EXTERNAL STERILIZABLE PADDLES (PN 3009166)

The following paragraphs describe:

- About External Sterilizable Paddles
- Monitoring and Therapy Procedures
- Cleaning and Sterilizing

About External Sterilizable Paddles

External sterilizable paddles (Figure 5-15) are specifically designed to be used for cardiac defibrillation in a sterile environment. These paddles can be used for defibrillation, monitoring, and synchronized cardioversion and connect directly to the LIFEPAK 20 defibrillator/monitor.

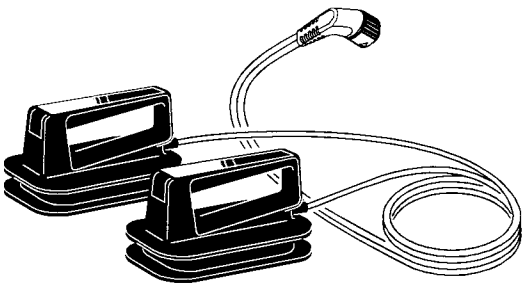


Figure 5-15 External Sterilizable Paddles

ECG Monitoring and Therapy Procedures

To use the external sterilizable paddles for ECG monitoring, defibrillation or synchronized cardioversion:

1 Connect the external sterilizable paddle cable to the therapy cable connector on the defibrillator. (For detailed instructions, refer to page 2-8.)

2 Proceed with ECG monitoring, defibrillation, or synchronized cardioversion as described in Section 3 or Section 4.

Note: To select energy, charge, or discharge, use the controls on the front panel, Area 1 (see page 2-4).

Cleaning and Sterilizing

Individually protect paddles before and after cleaning to prevent damage to paddle surfaces. After each use:

1 Wipe or rinse paddle surfaces, cable connector, paddle handles, and cables with mild soap and water or disinfectant using a damp sponge, towel or brush. Do not immerse or soak.

2 Dry thoroughly.

3 Examine paddles, handles, cables, and connector for damage or signs of wear.

Cables showing signs of wear such as loose cable connections, exposed wires, or cable connector corrosion should be removed from use immediately. Paddles with rough or pitted electrodes should be removed from use immediately.

4 Coil cable loosely away from the paddle to sterilize. Wrapping cable around the paddle may damage the cable.

External sterilizable paddles are approved for ethylene oxide gas or hydrogen peroxide plasma sterilization. The frequency of sterilization, rather than the age of the paddle, affects the useful life of the posterior defibrillation paddle. Refer to Cleaning and Sterilization Guidelines, page 5-14.

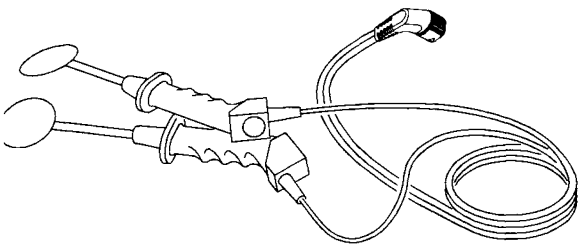
INTERNAL HANDLES WITH DISCHARGE CONTROL (PN 3010901)

The following paragraphs describe:

- About Internal Handles with Discharge Control
- Inserting the Paddles
- Removing the Paddles
- Internal Defibrillation Procedure
- Internal Paddles Synchronized Cardioversion Procedure
- Cleaning and Sterilizing
- Testing

About Internal Handles with Discharge Control

nternal handles with discharge control (Figure 5-16) are specifically designed for open chest cardiac lefibrillation and connect directly to the LIFEPAK 20 defibrillator/monitor.



igure 5-16 Internal Handles with Discharge Control

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Internal handles with discharge control are designed to be used only with internal paddles that have the cam locking end as shown in Figure 5-17. No other paddles are compatible with these handles.

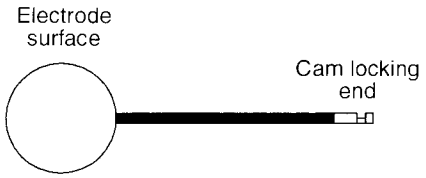


Figure 5-17 Internal Paddle

The internal paddles are available in the sizes listed in Table 5-2:

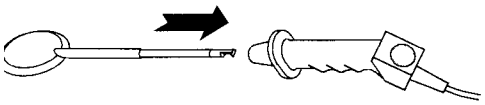
Table 5-2 Paddle Part Numbers

Size in Centimeters	Size in Inches	Part Number
2.5 cm	1.0 in.	805355-10
3.8 cm	1.5 in.	805355-11
5.1 cm	2.0 in.	805355-12
6.4 cm	2.5 in.	805355-13
8.9 cm	3.5 in.	805355-14

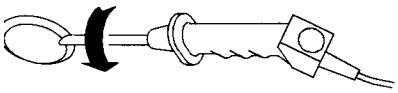
nserting the Paddles

To insert the paddles:

1. Using a sterile technique, insert paddle fully into handle until a positive stop is reached.



2. Press and rotate the paddle as shown (clockwise) until a second stop is reached.



3. Release the paddle to lock in place. A correctly installed and locked paddle cannot be directly withdrawn or rotated.

Removing the Paddles

To remove the paddles:

Push the paddle into the handle until a positive stop is reached.

Rotate the handle counterclockwise until a second stop is reached.

Slide the paddle out of the handle.

nternal Defibrillation Procedure

When internal handles are connected, energy selection is automatically limited to 50 J because of possible cardiac damage from higher energies. To initiate internal defibrillation:

Press ON. The Joules Selected symbol appears on the screen.

Press ENERGY SELECT if energy other than 10 J is desired.

Press CHARGE.

4 Place conductive surface of paddles against the right atrium and left ventricle.
5 Make certain that all personnel, including the operator, are clear of the patient, operating table or bed, or any other equipment connected to the patient.
6 Press the discharge control located on the internal handle when the defibrillator has reached the selected energy level. The defibrillator will not discharge until it completes charging to the selected energy level. If discharge control is not pressed within 60 seconds, stored energy is removed automatically.
7 Press the Speed Dial to manually remove an unwanted charge.

Internal Paddles Synchronized Cardioversion Procedure

When internal paddles are connected, the energy selection is automatically limited to 50 joules. To use internal paddles for synchronized cardioversion:

1 Connect the internal paddles to the defibrillator.
2 Turn on the defibrillator, and then select Paddles lead.
3 Change the ECG size (gain) to the lowest setting, 0.25.
4 Place the conductible surface of the paddles against the patient's atrium and ventricle.
5 Select the desired energy setting.
6 Press SYNC.
7 Confirm that a stable ECG signal is present and that triangle sense markers appear near the middle of each QRS complex.

Note: The patient's ECG acquired through internal paddles may be unreliable for synchronized cardioversion due to excessive noise or artifact, causing inappropriate R-wave detection. If the sense markers do not appear or are displayed in the wrong location (for example, on the T-wave), acquire the patient's ECG through standard ECG electrodes and cable.

8 Press CHARGE.
9 Make certain that all personnel, including the operator, are clear of the patient, operating table or bed, or any other equipment that is connected to the patient.
10 When the defibrillator reaches the selected energy level, press and hold the discharge control located on the internal handle. Discharge will occur with the next detected QRS complex.
11 Observe the patient's ECG rhythm.
12 If necessary, repeat steps 4 through 11.

Handling Internal Paddles

Observe the following precautionary measures to avoid damage to the coating on internal paddles.

- Immediately following surgery and after removing the handle(s), cover each paddle to help protect the paddles from impact to each other, other instruments, or hard surfaces.
- Use caution while handling the paddles during and after cleaning and before the sterilization wrapping process.
- Inspect the paddles for chips and scratches after each use. If any damage is found, remove the paddle(s) from use immediately.
- Ensure each paddle surface is protected from direct contact with the other while inside the sterilization wrapping.

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Cleaning and Sterilizing

Individually protect paddles before and after cleaning to prevent damage to paddle surfaces. After each use:

1 Detach paddles from handle.

2 Wipe or rinse paddles, handles, and cables with mild soap and water using a damp sponge, towel or brush. Do not immerse or soak.

3 Examine handles, cables and connector for damaged pins or signs of wear (i.e., loose cable connections, exposed wires, and cable connector corrosion). Examine paddles for scratched or pitted electrode surfaces and bubbled, scratched or chipped coating. If any of these conditions are found, remove the affected component from use immediately.

4 Coil cables loosely away from handles. Damage may occur if cables have tight bends or are wrapped around the handles.

nternal handles and paddles with discharge control may be ethylene oxide gas, steam, or hydrogen peroxide plasma sterilized. The useful life of internal paddles and handles is affected by the number of sterilization cycles rather than age. Refer to Cleaning and Sterilization Guidelines, page 5-14.

Testing

Perform comprehensive electrical testing using a defibrillator analyzer no less than quarterly or after ten sterilization cycles, whichever comes first.

CLEANING AND STERILIZATION GUIDELINES

The following paragraphs provide current cleaning and sterilization guidelines for therapy paddle accessories compatible with the LIFEPAK 20 defibrillator/monitor. The therapy paddle accessories covered by this guideline are:

Internal handles with discharge control (PN 3010901)

Internal paddles (PN 805355)

External sterilizable paddles (PN 3009166)

Posterior paddle (PN 802461)

Cleaning

After each use:

Remove detachable paddle(s) from handle(s).

Manually wipe or rinse paddles, handles, cables, and connectors with mild soap and water or disinfectant using damp sponge, towel, or brush. Do not immerse or soak (except for removable internal and posterior paddle electrodes).

Dry thoroughly.

Individually protect paddles before and after cleaning to prevent damage to paddle surfaces.

Examine handles, cables, and connector for damage or signs of wear (that is, loose cable connections, damaged pins, exposed wires, and cable connector corrosion). Examine paddles for scratched, pitted, or chipped electrode surfaces and bubbled, scratched, or chipped epoxy coating. If any of these conditions are found, remove the affected component from use immediately.

Steam Sterilization (Internal Handles and Paddles Only)

Medtronic has tested and approved LIFEPAK 20 defibrillator/monitor therapy paddle accessories: internal handles (PN 3010901) and internal paddles (PN 805355) for material compatibility and sterilization efficacy up to 200 cycles of steam sterilization, wrapped and unwrapped, using the following parameters.

Parameter	Prevacuum (Wrapped)	Gravity (Wrapped)	Flash Gravity (Unwrapped)
Sterilization Temperature	132° to 135°C (270° to 275°F)	132° to 135°C (270° to 275°F)	132° to 135°C (270° to 275°F)
Preconditioning Pulses	4 pulses	N/A	N/A
Prevacuum	10.0 inHg maximum	N/A	N/A
Pressure	30.5 psig maximum	30.5 psig maximum	30.5 psig maximum
Sterilization Exposure Time	4 minutes	30 minutes	12 minutes
Dry Time	Up to 30 minutes	Up to 30 minutes	Up to 30 minutes

The accessories were wrapped using sequential wrapping with single 66 cm x 40.6 cm (26 in. x 16 in.) woven cotton first wrap (square wrapped) and 61 cm x 61 cm (24 in. x 24 in.) nonwoven, bonded double thickness final wrap (envelope wrapped). Do not use peel packaging.

These sterilization parameters are valid only with equipment properly maintained and calibrated. Sterilization cycle times and efficacy vary depending on equipment, wrapping, and load configuration.

Internal handles must be positioned in the sterilizer to allow recessed paddle socket (lumen) area to drain.

Coil cables loosely away from handles during sterilization. Damage may occur if cables have tight bends or are wrapped around the handles. Individually protect internal paddles before and after sterilization to prevent damage to paddle surfaces.

The useful life of internal paddles is affected by the number of steam sterilization cycles rather than age. Paddle cycle life may be different between prevacuum sterilization and gravity displacement sterilization.

Ethylene Oxide Gas Sterilization (All Paddle Accessories)

Medtronic has tested and approved LIFEPAK 20 defibrillator/monitor therapy paddle accessories: internal handles (PN 3010901), internal paddles (PN 805355), external sterilizable paddles (PN 3009166), and posterior paddle (PN 802461) for material compatibility and sterilization efficacy to 100 cycles of ethylene oxide gas sterilization, wrapped (peel package) using the following parameters.

Parameter	100% EO (Wrapped)	12/88% EO (Wrapped)
Temperature	55°C (131 ±5°F)	55°C (131 ±5°F)
Humidity	40–80% RH	50–60% RH
Sterilant Gas	100% ethylene oxide	12% ethylene oxide/ 88% Dichlorodifluromethane
Concentration (ethylene oxide)	725 ±5% mg/L	600 ±5% mg/L
Sterilization Exposure Time	60 minutes	120 minutes
Aeration Time	11 hours (minimum) at 110 to 130°F	11 hours (minimum) at 110 to 130°F

STERRAD® Hydrogen Peroxide Gas Plasma Sterilization

Medtronic has tested and approved all LIFEPAK 20 defibrillator/monitor therapy paddle accessories: internal handles (PN 3010901), internal paddles (PN 805355), external sterilizable paddles (PN 3009166), and posterior paddle (PN 802461) for material compatibility and sterilization efficacy to 100 cycles of hydrogen peroxide gas plasma sterilization (STERRAD system), wrapped (STERRAD tray with double thickness SPUNGUARD® wrap or peel package) using the following parameters.

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Vacuum Phase:	Chamber evacuation to 300 mTorr pressure. Duration: 5–20 minutes
Injection Phase:	Automatic injection of 1.8 ml aqueous H2O2 solution and vaporization. Duration: 6–12 minutes
Diffusion Phase:	Diffusion of H2O2 in chamber and throughout load. Duration: 42 minutes
Plasma Phase:	Low temperature gas plasma with 400 W power at 500 mTorr pressure. Duration: 15 minutes
Vent Phase:	Chamber returned to atmospheric pressure.
Chamber Temperature:	Maintained at 45° to 55°C (113° to 131°F).
Total Cycle Time:	Approximately 75 minutes

The STERRAD System is an automated process with nonadjustable cycle parameters.

DATA MANAGEMENT

This section describes data management functions.

Overview of Data Storage and Retrieval	page 6-2
CODE SUMMARY Report	6-2
Managing Archived Patient Records	6-6
Entering Archives Mode	6-6
Printing Archived Patient Reports	6-7
Editing Archived Patient Records	6-8
Deleting Archived Patient Records	6-9
Overview of Connections for Transmitting Reports	6-11

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OVERVIEW OF DATA STORAGE AND RETRIEVAL

The following paragraphs describe patient data storage and retrieval using the LIFEPAK 20 defibrillator/monitor.

Data Storage

When you turn on the LIFEPAK 20 defibrillator/monitor, you create a new Patient Record stamped with the current date and time. All events and associated waveforms are digitally stored in the Patient Record as patient reports, which you can print. When you turn off the device, the current Patient Record data is saved in the patient archives.

To access the patient archives, press OPTIONS and select ARCHIVES. You can print or delete patient records stored in the archived Patient Record. When you enter the archives mode, patient monitoring ends and the current Patient Record is saved and closed. Turn off the device to exit the archives mode.

Report Types

Patient reports within a Patient Record are stored as a CODE SUMMARY™ Critical Event Record, which includes patient information, event and vital signs logs, and waveforms associated with events (for example, defibrillation) as described on page 6-4.

Memory Capacity

The LIFEPAK 20 defibrillator/monitor retains data for two or more patients when you switch power off or remove the batteries. The number of patient reports that the defibrillator can store depends on various factors, including the number of displayed waveforms, the duration of each use, and the type of therapy. Typically, memory capacity includes up to 100 single waveform reports. When the defibrillator reaches the limits of its memory capacity, the defibrillator deletes an entire Patient Record using a "first in, first out" priority to accommodate a new Patient Record. Deleted Patient Records cannot be retrieved.

CODE SUMMARY REPORT

The LIFEPAK 20 defibrillator/monitor automatically stores a CODE SUMMARY report as part of the Patient Record for each patient. The report consists of the following:

- Preamble
- Event/vital signs log
- Waveforms associated with certain events

Figure 6-1 is an example of a CODE SUMMARY report. Press CODE SUMMARY to print the report.

Preamble

Name:	**DAVIDO, GUIDO**	**CODE SUMMARY™**		
ID	041495094322	**critical event record**		
Patient ID:	52876004	Power On:	24 April 00	06:03:12
Location:	L483	Device:		100
Age: 45	Sex: M	Site:		ABCD
		Total Shocks:		3
		Total time paced		00:15:00
		Elapsed Time:		00:52:43

35.1 3434 LP20PRB005

Event/Vital Signs Log

Time	Event	HR	SpO2•PR	COMMENTS:
07:15:34	Power On			
07:16:34	Initial Rhythm	95	99•95	
07:20:34	Vital Signs	92	98•94	
07:22:14	Pacing 1 Started	95	98•95	
07:24:34	Pacing 2 Set	99	98•99	
07:25:34	Vital Signs	92	98•93	
07:26:36	Alarm HR	152	99	

Figure 6-1 CODE SUMMARY Report

Preamble

The preamble contains patient information (name, event identification, patient identification, location, age, and sex) and device information (date, time, and therapy information) as shown in Figure 6-1. The event identification is a unique identifier that the defibrillator automatically enters in the ID field for each Patient Report. This identifier is composed of the date and time that the defibrillator is turned on. The location field allows you to enter up to 25 alpha-numeric characters to identify where the device was used. You can link the data you enter to other patient information.

Event/Vital Signs Log

The LIFEPAK 20 defibrillator/monitor documents events and vital signs in chronological order. Events are operator or device actions that are related to monitoring, pacing, AED therapy, data transmission, and more. Table 6-1 shows a complete listing of events that can be found in the event log.

Vital signs (or active parameters) are entered into the log automatically every 5 minutes (or for each event; see AUTO LOG in Table 8-1) and when alarm limits are exceeded.

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Table 6-1 Event Types

Event Types	Events			
Monitoring	• Initial rhythm	• Alarm events	• Vital signs	
Operator initiated	• Event	• Print	• Sync On/Off	• Internal Pacer Detection On/Off
	• Alarms On	• VF/VT Alarm On/ Off		
Therapy AED	• AED mode	• Connect electrodes	• Analysis	• Shock advised
	• Check patient	• Motion	• Analysis stopped	• No shock advised
Defibrillation	• Manual mode	• Charge removed	• Shock X Delivered	• Shock X Not Delivered
Pacing	• Started	• Set	• Changed	• Stopped
	• Paused			
Memory Status	• Out of Waveform Memory [memory low]	• Out of Event Memory [memory full]		

Waveform Events

In addition to being documented in the Event Log, therapy and other selected events also capture waveform data as described in Table 6-2.

Table 6-2 Waveform Events

Event Name	Waveform Data
INITIAL RHYTHM	• 8 seconds after leads on.
CHECK PATIENT	• 8 seconds prior to alert.
SHOCK **or** NO SHOCK ADVISED	• 2–3 segments of analyzed ECG. Each segment may be 2.7 seconds.
ANALYSIS X STOPPED	• 8 seconds of data prior to cessation of analysis.
SHOCK X	• 3 seconds prior to shock and 5 seconds after shock.
PACING X STARTED	• 8 seconds prior to increase of current from 0.
PACING X SET	• 8 seconds after ppm and mA are stable for 10 seconds.
PACING X CHANGED	• 8 seconds after pacing rate, current, or mode is changed.
PACING X STOPPED	• 3 seconds prior to pacing current is zero and 5 seconds after.
PACING X PAUSED	• Initial 8 seconds while PAUSE is pressed.
ALARM*	• 3 seconds prior to violated parameter and 5 seconds after.
EVENT*	• 3 seconds prior to event selection and 5 seconds after.
PRINT	• 3 seconds prior to pressing PRINT and 5 seconds after.

To reduce the length of the CODE SUMMARY report, storing waveform data with these events can be configured OFF (see page 8-8).

Waveform events are preceded by a header that includes the following information:

Patient data	• Vital signs
Event name	• Device configuration information
Therapy data	• Transthoracic impedance measured during the shock (defibrillation events only)

CODE SUMMARY Format

You can configure the LIFEPAK 20 defibrillator/monitor to print a CODE SUMMARY report in one of the formats described in Table 6-3. CODE SUMMARY reports are always stored in the medium format.

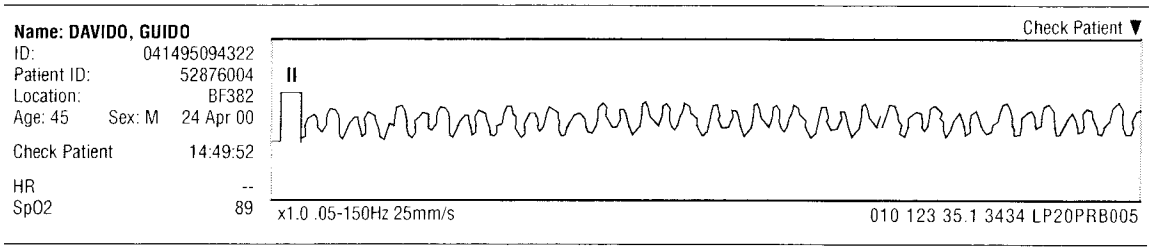
Table 6-3 CODE SUMMARY Formats

Format	Attributes	
Medium format	• Preamble • Event/vital signs log	• Event waveforms
Short format	• Preamble	• Event/vital signs log

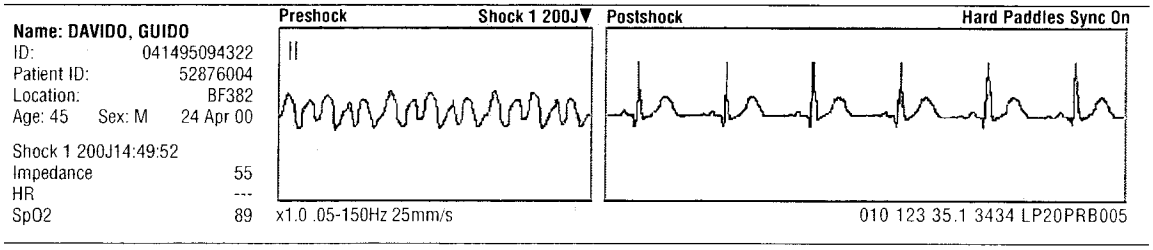
The format determines only which reports are printed when the CODE SUMMARY button is pressed. If you interrupt printing of a CODE SUMMARY report, the entire CODE SUMMARY report will be reprinted when printing is resumed.

CODE SUMMARY Complete is printed immediately following the last waveform event.

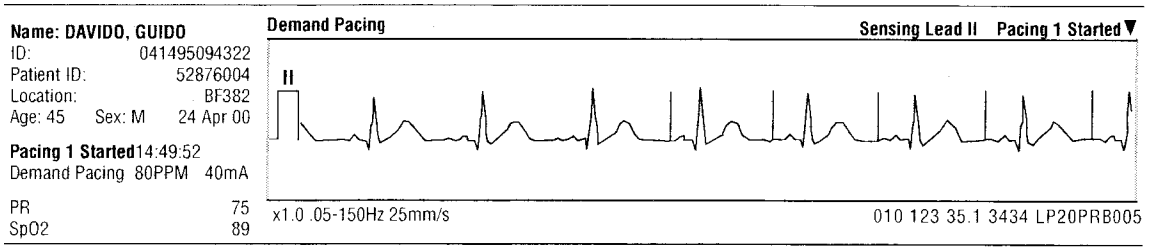
See Figure 6-2 for examples of waveform data event printouts in the CODE SUMMARY report.



Check Patient Event



Defibrillation Event



Pacing Event

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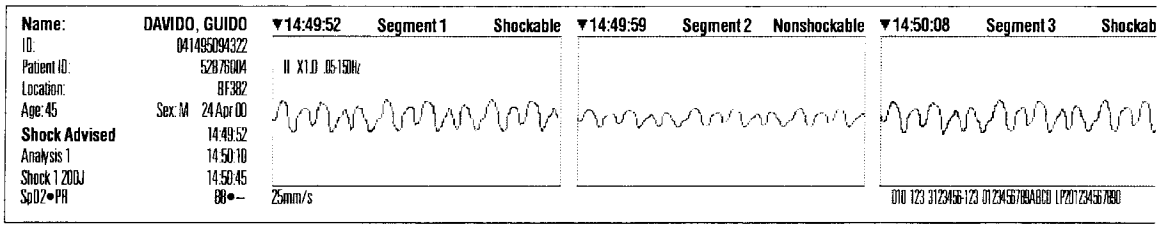
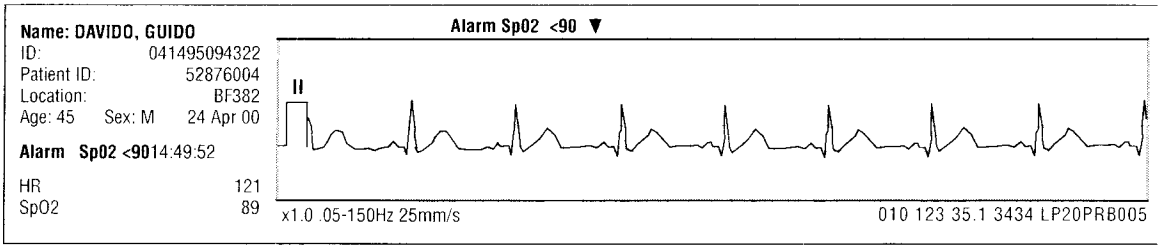


SAS Event



Parameter Alarm Event

Figure 6-2 Waveform Event Printout Examples

MANAGING ARCHIVED PATIENT RECORDS

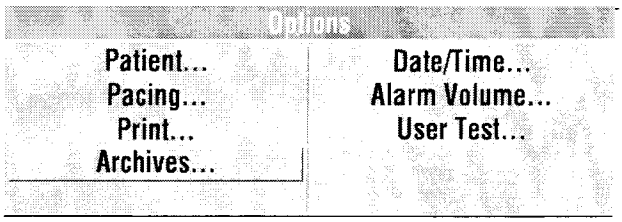
When you turn off the LIFEPAK 20 defibrillator/monitor, the current Patient Record is saved in the archives. There are three options for managing archived Patient Records:

- Print archived patient reports
- Edit archived patient records
- Delete archived patient records

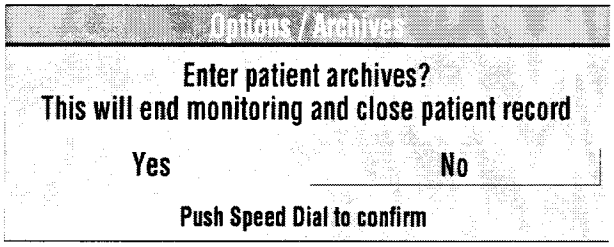
To perform any or all of these options, you must first enter the archives mode and then proceed with the desired option.

ENTERING ARCHIVES MODE

To enter the archives mode:



1 Press OPTIONS.
2 Select ARCHIVES.

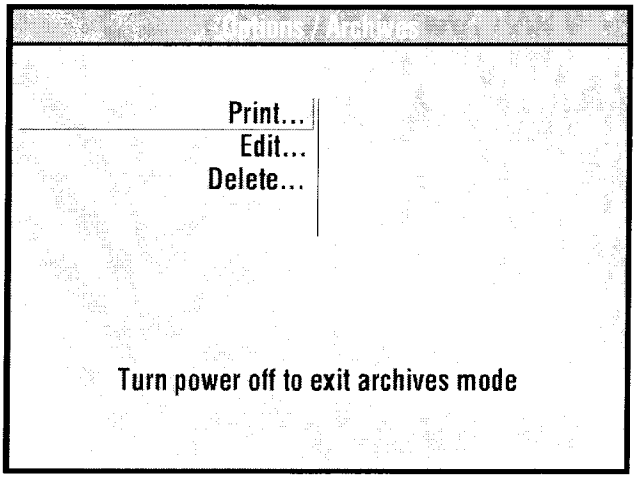


3 Select YES to enter the patient archives.
YES closes and saves the current Patient Record and ends patient monitoring.
–or–
Select NO to clear the overlay and return to the previous screen.

Note: When you enter the archives mode, patient monitoring ends (for example, no ECG, no alarms) and the current Patient Record is saved and closed.

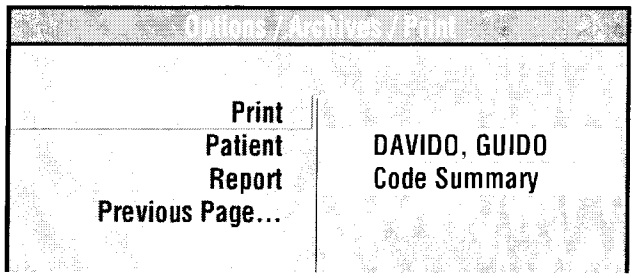
PRINTING ARCHIVED PATIENT REPORTS

To print:

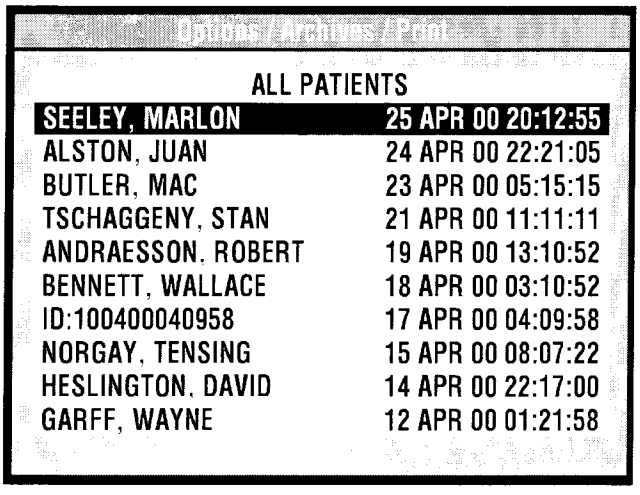


1 Be sure that you are in the archives mode (refer to Entering Archives Mode, page 6-6).

2 Select PRINT.



3 If the PATIENT and REPORT settings are correct, select PRINT to print the report. Otherwise, select PATIENT and proceed to the next step.


Options / Archives / Print
ALL PATIENTS
SEELEY, MARLON 25 APR 00 20:12:55
ALSTON, JUAN 24 APR 00 22:21:05
BUTLER, MAC 23 APR 00 05:15:15
TSCHAGGENY, STAN 21 APR 00 11:11:11
ANDRAESSON, ROBERT 19 APR 00 13:10:52
BENNETT, WALLACE 18 APR 00 03:10:52
ID:100400040958 17 APR 00 04:09:58
NORGAY, TENSING 15 APR 00 08:07:22
HESLINGTON, DAVID 14 APR 00 22:17:00
GARFF, WAYNE 12 APR 00 01:21:58

4 Select a patient from the list of Patient Records or select ALL PATIENTS to print a list of all Patient Records in the archives.

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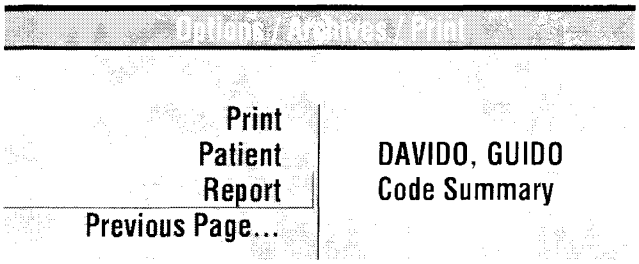
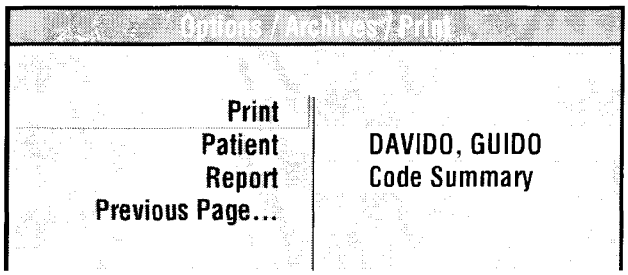


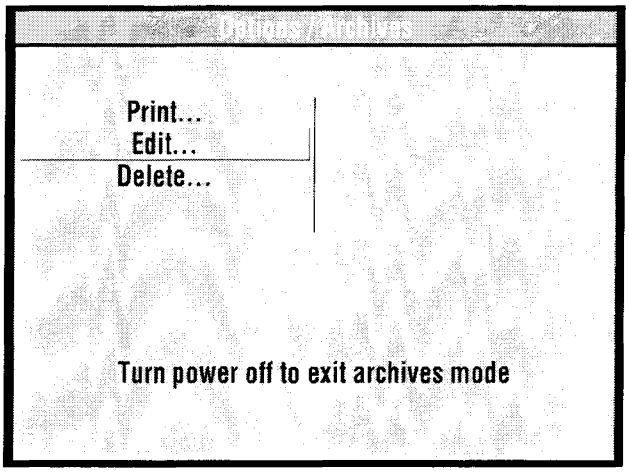
5 Select REPORT to display the report list:
CODE SUMMARY – Prints the CODE SUMMARY report (medium format).
A check mark indicates that a report was previously printed.



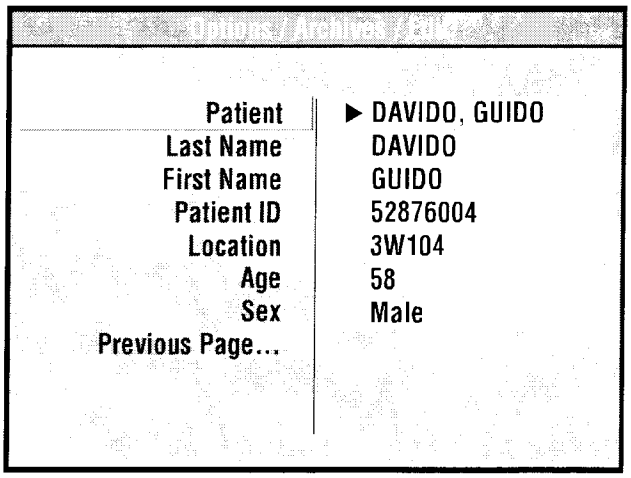
6 Select PRINT.
To return to the Options/Archives menu, press HOME SCREEN.
–or–
To exit the archives mode, turn off the device.

EDITING ARCHIVED PATIENT RECORDS

To edit:



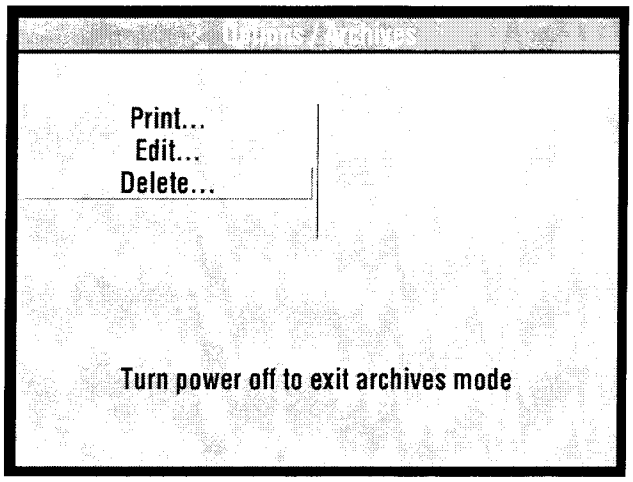
1 Be sure that you are in the archives mode (refer to Entering Archives Mode, page 6-6).
2 Select EDIT.



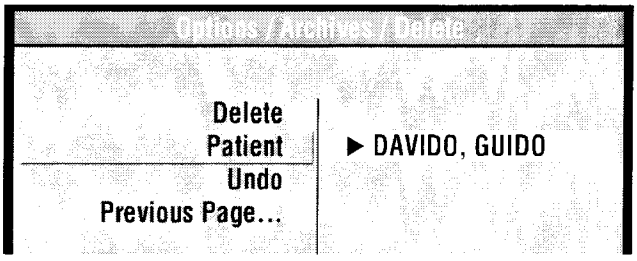
3 Select PATIENT.
4 Add or change the necessary patient information.
5 Press HOME SCREEN, then turn off the device.

DELETING ARCHIVED PATIENT RECORDS

To delete:



1 Be sure that you are in the archives mode (refer to Entering Archives Mode, page 6-6).
2 Select DELETE.



3 Select PATIENT.

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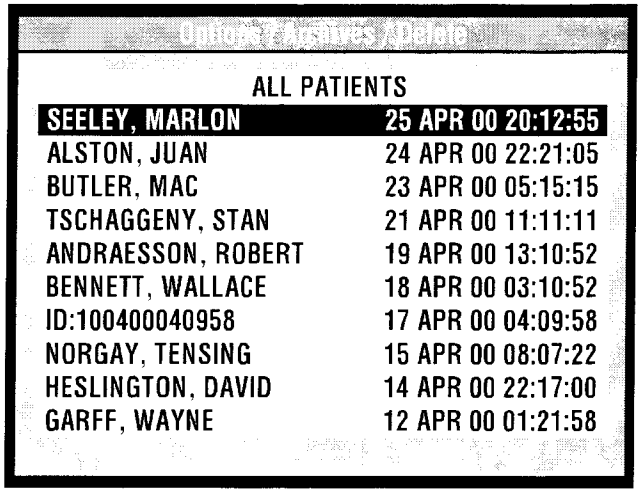
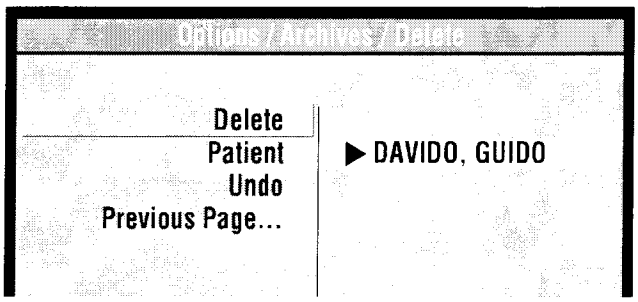

Options / Archives / Delete
ALL PATIENTS
SEELEY, MARLON 25 APR 00 20:12:55
ALSTON, JUAN 24 APR 00 22:21:05
BUTLER, MAC 23 APR 00 05:15:15
TSCHAGGENY, STAN 21 APR 00 11:11:11
ANDRAESSON, ROBERT 19 APR 00 13:10:52
BENNETT, WALLACE 18 APR 00 03:10:52
ID:100400040958 17 APR 00 04:09:58
NORGAY, TENSING 15 APR 00 08:07:22
HESLINGTON, DAVID 14 APR 00 22:17:00
GARFF, WAYNE 12 APR 00 01:21:58

4 Select a patient from the list.



5 Select DELETE to permanently remove the selected Patient Record from the archives.

Note: If, after you select DELETE, you decide you do not want to remove the patient record, immediately select UNDO. If you continue operations, you cannot reverse the DELETE selection.

6 Press HOME SCREEN and then turn off the device.

OVERVIEW OF CONNECTIONS FOR TRANSMITTING REPORTS

Patient reports can be transmitted from the LIFEPAK 20 defibrillator/monitor to a PC-compatible computer equipped with the Medtronic CODE-STAT™ Suite medical informatics system (version 5.x or later). CODE-STAT Suite is compatible with a wide range of Microsoft® Windows® operating systems: Windows 98 SE, Windows 2000 Professional, Windows ME, Windows NT Workstation, and Windows XP.

An IrDA port, located on the front of the LIFEPAK 20 defibrillator/monitor (see page 2-8), supports wireless, infrared communications for transmitting reports from the defibrillator to your computer. To receive the transmission, your computer must have an operational IrDA port.

If your computer does not have an IrDA port, you can install an IrDA adapter to provide the needed interface. Medtronic recommends installing an IrDA adapter on all computers to ensure successful communication connections and data transmissions.

IrDA adapters are available for serial or USB computer ports. Follow the installation and usage instructions provided with the adapter, ensuring that the adapter mount (receiving end) is positioned on a stable surface. Figure 6-3 provides guidelines to follow for positioning the defibrillator and the IrDA adapter before initiating a transmission.

Note: The shaded cone in Figure 6-3 represents the approximate parameters for positioning the defibrillator's IrDA port opposite the IrDA adapter. As the distance between the two increases, so does the possible range for aligning them.

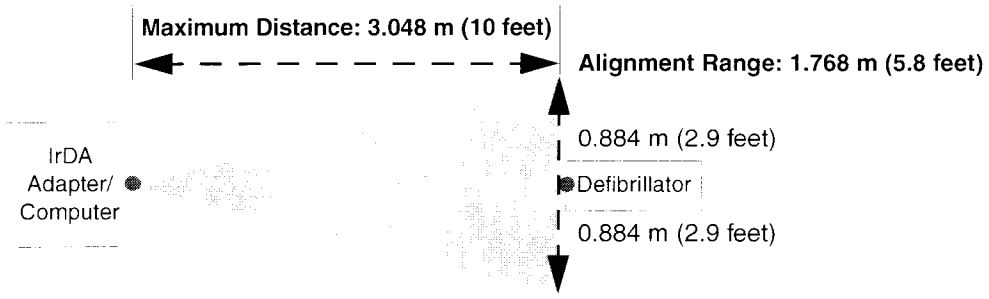


Figure 6-3 IrDA Connections

You initiate and control transmission of device data at your computer using CODE-STAT Suite. This includes entering patient information, selecting reports to be transmitted, and monitoring transmission progress. More information about configuring the CODE-STAT Suite medical informatics system and instructions for transmitting device data are provided in the users guide and reference cards that accompany your CODE-STAT Suite System.

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MAINTAINING THE EQUIPMENT

This section describes how to perform operator-level maintenance, testing, and troubleshooting for the LIFEPAK 20 defibrillator/monitor and selected accessories. For additional information about accessories, refer to specific accessory operating instructions.

General Maintenance and Testing	page 7-2
General Troubleshooting Tips	7-10
Service and Repair	7-12
Product Recycling Information	7-12
Warranty	7-13
Accessories, Supplies, and Training Tools	7-13

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GENERAL MAINTENANCE AND TESTING

Periodic maintenance and testing of the LIFEPAK 20 defibrillator/monitor and accessories will help detect and prevent possible electrical and mechanical discrepancies. If testing reveals a possible discrepancy with the defibrillator or accessories, refer to General Troubleshooting Tips, page 7-10. If the discrepancy cannot be corrected, immediately remove the device from service and contact qualified service personnel. For testing information regarding accessories, refer to the accessory operating instructions.

Each time you turn on the defibrillator/monitor, it performs self tests. If the defibrillator/monitor detects a failure, the service LED illuminates.

A *MAINTENANCE DUE* message can be configured to appear on the screen at selected intervals (3, 6 or 12 months) to remind you that the device is due for maintenance. The factory default is OFF, but it can be activated by service personnel.

Maintenance and Testing Schedule

Table 7-1 lists the recommended maintenance and testing schedule. This schedule may be used in conjunction with the internal quality assurance program of the hospital, clinic, or emergency medical service where the defibrillator is used. An Operator's Checklist is included in these operating instructions (refer to Appendix D).

Additional periodic preventive maintenance and testing, such as electrical safety tests, performance inspection, and required calibration should be performed regularly by qualified service personnel.

Table 7-1 Recommended Maintenance Schedule

Operation	Daily	After Use	As Required	3 Months	6 Months	12 Months
Complete Operator's Checklist (see Appendix D).	X		X			
Inspect defibrillator.		X	X			
Clean defibrillator.		X	X			
Check that all necessary supplies and accessories are present (for example, gel, electrodes, ECG paper, etc.).		X	X			
Daily auto test	X					
User test			X			
Function Checks:						
AED check					X	
Standard paddles monitoring check					X	
Standard paddles defibrillation check					X	
Standard paddles synchronized cardioversion check					X	
Therapy cable monitoring check					X	
Therapy cable defibrillation check					X	
Therapy cable synchronized cardioversion check					X	
Therapy cable pacing check					X	
Preventive maintenance and testing.						X

Daily Auto Test

Each day at approximately 0300 (3:00 am), the LIFEPAK 20 defibrillator/monitor automatically completes the following tasks:

- Turns itself on
- Performs self-tests
- Charges to approximately 10 J and then discharges through a test load
- Tests the pacing circuitry (if noninvasive pacing installed)
- Stores the results in the test log
- Prints the results, if configured ON
- Turns itself off

The daily auto test is not performed if the LIFEPAK 20 defibrillator/monitor is already turned on at 0300. If you must use the device while the daily auto test is in progress, press ON. The test is halted and the LIFEPAK 20 defibrillator/monitor resumes normal operation.

If the defibrillator detects a problem during the auto test, it will remain on if connected to ac power. The service LED will illuminate and the printed report will indicate a test failure. If the device is not connected to ac power, the service LED illuminates when the defibrillator is turned on again.

Note: It is important that the standard paddles set is properly seated in the paddle wells or that the QUIK-COMBO therapy cable is connected to the QUIK-COMBO test plug (see Figure 7-1) for the daily auto test to be completed. If not, the integrity of the therapy cables will not be tested and the defibrillator or pacer test will have to be performed manually using the user test provided in the Options menu.

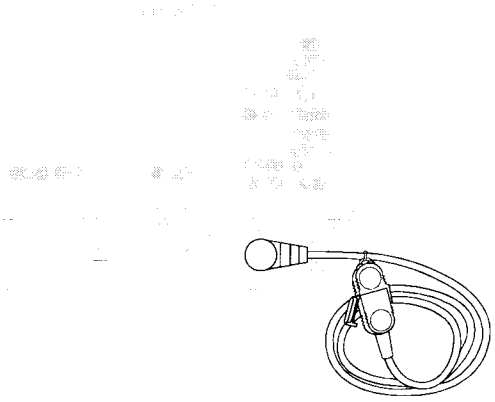

Figure 7-1 QUIK-COMBO Test Plug

User Test

The LIFEPAK 20 defibrillator/monitor user test is a functional test and should not be performed while using the defibrillator during patient care. To perform the user test, press OPTIONS and select USER TEST. This test may be performed in place of your daily defibrillator charging and discharging protocol. It is important that the standard paddles set is properly seated in the paddle wells or that the QUIK-COMBO therapy cable is connected to the QUIK-COMBO test plug (see Figure 7-1) for the user test to be completed.

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Press OPTIONS to access the user test. When selected, the user test automatically performs the following tasks:

- Turns itself on
- Performs self-tests
- Charges to approximately 10 J and then discharges through a test load
- Tests the pacing circuitry (if noninvasive pacing installed)
- Stores the results in the test log
- Prints the results
- Turns itself off

If the LIFEPAK 20 defibrillator/monitor detects a problem during the user test, the service LED lights and a printed report indicates that the test failed. Turn off the defibrillator and then repeat the user test. If the service LED remains lit, contact qualified service personnel.

If it is necessary to interrupt the user test, turn the power off and then on again. The test will stop and the defibrillator will operate normally. A Pass/Fail report will not print.

Note: During the user test, all front panel controls (except ON) and standard paddle controls are disabled. Routinely testing the defibrillator consumes power; perform the user test with the device plugged into ac power.

Note: It is important to understand defibrillator operation. Refer to page 7-2 through page 7-9 for suggested procedures to help ensure that personnel are acquainted with normal defibrillator operation and to troubleshoot device performance. The procedures used may vary according to your local protocols. To test the defibrillator by performing the function checks requires the use of an optional test load or simulator.

Cleaning

CAUTION!

Possible equipment damage.

Do not clean any part of this device or accessories with bleach, bleach dilution, or phenolic compounds. Do not use abrasive or flammable cleaning agents. Do not attempt to sterilize this device or any accessories unless otherwise specified in accessory Operating Instructions.

Clean the LIFEPAK 20 defibrillator/monitor, cables, and accessories with a damp sponge or cloth. Use only the cleaning agents listed below:

Quaternary ammonium compounds

Isopropyl alcohol

Peracetic (peroxide) acid solutions

To clean the sensor, first remove it from the patient and disconnect it from the patient cable. You may then clean the LNOP DCI by wiping it with a 70% isopropyl alcohol pad. Allow the sensor to dry prior to placement on a patient.

Clean the PC patient cable by wiping it with a 70% isopropyl alcohol pad and allow it to dry. Do not soak or immerse the cable in any liquid solution. Do not attempt to sterilize.

Function Checks

CAUTION!

Possible simulator damage.

Do not discharge more than 30 shocks within an hour or 10 shocks within a five-minute period, or pace continually into Medtronic patient simulators. Simulators may overheat.

The following function checks are provided to help personnel keep acquainted with normal operating procedures and to troubleshoot device performance.

Older Medtronic simulators and testers respond differently to defibrillators configured with a biphasic defibrillation waveform. QUIK-COMBO simulators (PN 806223 and PN 803499) require a 275 J biphasic shock to change simulated VF rhythm to NSR. Sometimes no amount of energy can change the simulated VF rhythm. The pace LED flashes when the shock does not change the simulated rhythm.

Newer QUIK-COMBO simulators (PN 806223 and PN 806395) respond appropriately to defibrillators with a biphasic defibrillation waveform. If using the Medtronic Patient Simulator (PN 803499), the defibrillator LED may not flash at any energy level. For further information, in the USA, call 1.800.442.1142. Outside the USA, contact your local Medtronic representative.

Patient ECG Cable Check

Equipment needed:

- LIFEPAK 20 defibrillator/monitor
- Fully charged batteries
- Patient ECG cable (3-wire or 5-wire)
- 3-lead or 12-lead simulator

Procedure:

1. Press ON.
2. Connect the ECG cable to the defibrillator.
3. Connect all cable leads to the simulator.
4. Turn on the simulator and select a rhythm.
5. After a few seconds confirm that the screen displays a rhythm and no *LEADS OFF* or *SERVICE* messages appear.

AED Check

Equipment needed:

LIFEPAK 20 defibrillator/monitor

QUIK-COMBO or FAST-PATCH therapy cable

QUIK-COMBO 3-lead or 12-lead patient simulator, posted patient simulator, or test plug.

Procedure:

Press ON.

2. Connect the therapy connector to the simulator or test load.
3. If using the simulator, select VF rhythm.
4. Turn on the simulator.
5. Following the voice prompt, press ANALYZE.
6. Confirm the ANALYZING NOW - STAND CLEAR voice and screen prompts.

   If connected to the simulator, confirm the SHOCK ADVISED voice and screen prompts and that the tone (indicating full charge) sounds within 10 seconds.

   If connected to the test plug, confirm the NO SHOCK ADVISED voice and screen prompts. Press the SHOCK button following the CHECK FOR PULSE - IF NO PULSE, START CPR prompt and confirm the key click.

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Standard Paddles Monitoring Check

Equipment needed:

- LIFEPAK 20 defibrillator/monitor
- Standard paddles

Procedure:

1 Press ON.
2 Select paddles lead.
3 Press the paddle electrode surfaces together and confirm that a flat line appears.
4 Shake each paddle in the air and confirm that irregular noise signals appear.
5 Install the paddles in the paddle wells.

Standard Paddles Defibrillation Check

WARNING!

Shock hazard.

When discharged as described in this test, the defibrillator delivers up to 360 J of electrical energy. Unless discharged properly as described in this test, this electrical energy may cause serious personal injury or death. Do not attempt to perform this test unless you are qualified by training and experience and thoroughly familiar with these Operating Instructions.

Equipment needed:

LIFEPAK 20 defibrillator/monitor
Standard paddles
Fully charged batteries
Defibrillator checker

Procedure:

Press ON.
Place the standard paddles on the defibrillator checker paddle plates.
Select 200 J.
Press CHARGE.
Confirm that the tone indicating full charge sounds within 10 seconds or less.
Press only the apex SHOCK button and confirm that the defibrillator does not discharge. Release the apex SHOCK button.
Press only the sternum SHOCK button and confirm that the defibrillator does not discharge. Release the sternum SHOCK button.
Press PRINT.

WARNING!

Possible paddle damage and patient burns.

Press paddles firmly onto test load plates when discharging to prevent arcing and formation of pits on paddle surfaces. Pitted or damaged paddles may cause patient skin burns during defibrillation.

Apply firm pressure with both paddles on the defibrillator checker plates and press both paddle SHOCK buttons simultaneously.
10 Confirm that the defibrillator discharges.
11 Confirm that the printer annotates the time, date, and energy selected on the ECG strip.

Standard Paddles Synchronized Cardioversion Check

WARNING!

Shock hazard.

When discharged as described in this test, the defibrillator delivers up to 360 J of electrical energy. Unless discharged properly as described in this test, this electrical energy may cause serious personal injury or death. Do not attempt to perform this test unless you are qualified by training and experience and are thoroughly familiar with these operating instructions.

Equipment needed:

- LIFEPAK 20 defibrillator/monitor
- Standard paddles
- Defibrillator checker
- Patient ECG cable
- 3-lead or 12-lead patient simulator
- Fully charged batteries

Procedure:

1 Press ON.

2 Connect the ECG cable.

3 Connect the ECG cable to the monitor and the patient simulator.

4 Place the standard paddles on the defibrillator checker paddle plates.

5 Turn on the simulator and select any rhythm except asystole or ventricular fibrillation.

6 Select Lead II.

7 Press SYNC. Confirm the sync LED lights. Adjust ECG size until the sense markers appear on the QRS complexes. Confirm that the sync LED blinks off with each detected QRS complex and the heart rate is displayed.

8 Select 50 J.

9 Press CHARGE.

10 Press PRINT.

11 After the tone sounds indicating full charge:

- Apply firm pressure with both paddles on the defibrillator checker.

WARNING!

Possible paddle damage and patient burns.

Press paddles firmly onto test load plates when discharging to prevent arcing and formation of pits on paddle surfaces. Pitted or damaged paddles may cause patient skin burns during defibrillation.

- Simultaneously press and **hold** both discharge buttons while observing the screen.

12 Confirm the defibrillator discharges on the next sensed QRS complex.

13 Confirm the defibrillator returns to asynchronous mode (sense markers are no longer displayed and the sync LED is off).

Note: The defibrillator may be configured to remain in synchronous mode after discharge.

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Therapy Cable Monitoring Check

Equipment needed:

- LIFEPAK 20 defibrillator/monitor
- QUIK-COMBO™ (or FAST-PATCH®) therapy cable
- QUIK-COMBO 3-lead or 12-lead patient simulator, or posted patient simulator
- Fully charged batteries

Procedure:

1 Press ON.
2 Turn on the simulator and select normal sinus rhythm.
3 Connect the therapy cable to the patient simulator.
4 Select paddles lead.
5 Confirm that the screen shows a normal sinus rhythm and that no *PADDLES LEADS OFF* or *SERVICE* message appears.
6 Disconnect the therapy cable from the simulator. Confirm the *PADDLES LEADS OFF* message appears and an audible alarm sounds.

Therapy Cable Defibrillation Check

Equipment needed:

- LIFEPAK 20 defibrillator/monitor
- QUIK-COMBO or FAST-PATCH therapy cable
- QUIK-COMBO 3-lead or 12-lead patient simulator, posted patient simulator, or Medtronic test load
- Fully charged batteries

Procedure:

1 Press ON.
2 Connect the therapy cable to the simulator or test load.
3 Turn on the simulator.
4 Select 200 J.
5 Press CHARGE.
6 Confirm that the tone indicating full charge sounds within 10 seconds or less.
7 Press PRINT.

WARNING!

Shock hazard.

During defibrillation checks, the discharged energy passes through the cable connectors. Securely attach cable connectors to the simulator.

8 Press SHOCK.
9 Confirm that the defibrillator discharges.
10 Confirm that the printer annotates the time, date, and energy selected on the ECG strip.
11 Disconnect the therapy cable from the simulator.
12 Confirm the *PADDLES LEADS OFF* message appears and an audible alarm sounds.

Therapy Cable Synchronized Cardioversion Check

Equipment needed:

- LIFEPAK 20 defibrillator/monitor
- QUIK-COMBO (or FAST-PATCH) therapy cable
- Patient ECG cable
- QUIK-COMBO 3-lead or 12-lead patient simulator, or posted patient simulator
- Fully charged batteries

Procedure:

1 Press ON.
2 Connect the ECG cable to the defibrillator and the simulator.
3 Connect the therapy cable to the simulator.
4 Turn on the simulator and select any rhythm except asystole or ventricular fibrillation.
5 Select Lead II.
6 Press SYNC.
7 Confirm that the sync LED lights. Adjust ECG size until sense markers appear on the QRS complexes.
8 Confirm that the sync LED blinks off with each detected QRS complex and that the heart rate is displayed.
9 Select 50 J.
10 Press CHARGE.
11 Press PRINT.

WARNING!

Shock hazard.

During defibrillation checks, the discharged energy passes through the cable connectors. Securely attach cable connectors to the simulator.

12 After the tone sounds indicating full charge, press and hold SHOCK while observing the monitor screen.
13 Confirm that the defibrillator discharges on the next sensed QRS complex.
14 Confirm that the defibrillator returns to asynchronous mode (sense markers are no longer displayed and sync LED is off).
15 Disconnect the therapy cable from the simulator and confirm the *PADDLES / PADS OFF* message appears and an audible alarm sounds.

Note: The defibrillator may be configured to remain in synchronous mode after discharge.

Therapy Cable Pacing Check

Equipment needed:

LIFEPAK 20 defibrillator/monitor
QUIK-COMBO therapy cable
Patient ECG cable
QUIK-COMBO 3- or 12-lead patient simulator
Fully charged batteries

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Procedure:

1 Press ON.
2 Connect the QUIK-COMBO therapy cable to the QUIK-COMBO simulator.
3 Turn on the simulator and select BRADY.
4 Connect the ECG cable to the defibrillator and the simulator.
5 Select Lead II.
6 Press PACER.
7 Confirm that sense markers appear on each QRS complex. If sense markers do not appear, or appear elsewhere on the ECG, press the selector on waveform Channel 1 and adjust ECG size on the overlay.
8 Confirm that the Rate overlay appears.
9 Press CURRENT and increase the current to 80 mA.
10 Observe the screen for captured complexes. Confirm the pacer LED flashes with each delivered pacing pulse.
11 Disconnect the QUIK-COMBO therapy cable from the simulator. Confirm that the pacemaker stops pacing, the *CONNECT ELECTRODES* message appears, and an audible alarm sounds.
12 Reconnect the QUIK-COMBO therapy cable to the simulator. Confirm that the audible alarm stops, the *PACING STOPPED* message displays, and that the current is 0 mA.
13 Increase current to 80 mA.
14 Press CHARGE. Confirm the pacer LED goes off and the heart rate and available energy display on the screen.

GENERAL TROUBLESHOOTING TIPS

f a problem with the defibrillator/monitor is detected during operation or testing, refer to the roubleshooting tips in Table 7-2. If the problem cannot be corrected, remove the defibrillator/monitor rom use and contact qualified service personnel.

able 7-2 General Troubleshooting Tips

Observation	Possible Cause	Corrective Action
1 No power when defibrillator/monitor is turned ON.	Low battery voltage.	• Connect to ac.
2 Defibrillator/monitor operates, but screen is blank.	Operating temperature is too low or too high.	• Connect to ac.
	Screen is not displaying properly.	• Contact qualified service personnel.
3 *CHECK PRINTER* message appears.	Printer paper jams, slips, or misfeeds.	• Reinstall paper.
	Printer is out of paper.	• Add new paper. • If problem persists, contact qualified service personnel.
4 No power when connected to ac power.	Loose or improper connection between defibrillator and power source.	• Check power connections and cables.

Table 7-2 General Troubleshooting Tips (Continued)

Observation	Possible Cause	Corrective Action
5 Service LED illuminates.	Device self-test circuitry detects service condition.	• Continue to use defibrillator or pacemaker if needed. • Turn device off then on again. Note that this creates a new Patient Record. • If service LED does not clear, remove device from active use. • Report occurrence of service LED to qualified service personnel.
6 ECG monitoring problems.		• Refer to Section 3, page 3-5.
7 Problems with AED operation.		• Refer to Section 4, page 4-6.
8 Problems with defibrillation/ synchronized cardioversion.		• Refer to Section 4, page 4-17.
9 Problems with pacing.		• Refer to Section 4, page 4-19.
10 Displayed time is incorrect.	Time is incorrectly set.	• Change the time setting. Refer to Section 2, page 2-7.
11 Date printed on report is incorrect.	Date is incorrectly set.	• Change the date setting. Refer to Section 2, page 2-7.
12 Displayed messages are faint or flicker.	Low battery power. Out of temperature range.	• Connect to ac power immediately.
13 Low speaker volume.	Moisture in speaker grill holes.	• Wipe moisture from speaker grill and allow device to dry.
14 *MAINTENANCE DUE* message appears.	Maintenance prompt is set to display at a selected interval in service mode.	• Continue to use device if needed. • Contact service personnel to reset or turn off the maintenance prompt. • Contact Medtronic technical services for instructions on how to reset or turn off this prompt.
15 *SELF TEST DID NOT COMPLETE* message appears	Test plug not connected to QUIK-COMBO therapy cable during daily auto test. Standard Paddles not seated in paddle wells during daily auto test.	• Connect test plug to QUIK-COMBO therapy cable for daily auto test. • Make sure Standard Paddles are securely seated in the paddle wells for daily auto test.
16 *SELF TEST FAILED* message appears	Device self test circuitry detects service condition during daily auto test.	• Use defibrillator or pacemaker if needed in an emergency. • Turn device off then on again. Note that this creates a new Patient Record. • If service LED does not clear, remove device from active use. • Report occurrence of service LED to qualified service personnel.

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Table 7-2 General Troubleshooting Tips (Continued)

Observation	Possible Cause	Corrective Action
17 *USER TEST DID NOT COMPLETE* message appears	Test plug not connected to QUIK-COMBO therapy cable during user test.	• Connect test plug to QUIK-COMBO therapy cable for user test.
	Standard Paddles not seated in paddle wells during user test.	• Make sure Standard Paddles are securely seated in the paddle wells for user test.
18 *USER TEST FAILED* message appears	Device self test circuitry detects service condition during user test.	• Use defibrillator or pacemaker if needed in an emergency. • Turn device off then on again. Note that this creates a new Patient Record. • If service LED does not clear, remove device from active use. • Report occurrence of service LED to qualified service personnel.

SERVICE AND REPAIR

WARNINGS!

Shock hazard.

Do not disassemble the defibrillator. It contains no operator serviceable components and dangerous high voltages may be present. Contact qualified service personnel for repair.

Possible ineffective energy delivery.

Service mode is for authorized personnel only. Improper use of service mode may inappropriately alter the device's configuration and may change energy output levels. Contact qualified service personnel for assistance or information about device configuration.

f testing, troubleshooting, or a service message indicates the LIFEPAK 20 defibrillator/monitor requires ;ervice, contact qualified service personnel. In the USA, call 1.800.442.1142. Outside the USA, contact /our local Medtronic representative.

When calling Medtronic to request service, identify the model and serial number and describe the)bservation. If the device must be shipped to a service center or the factory, pack the device in the)riginal shipping container, if possible, or in protective packing to prevent shipping damage.

The LIFEPAK 20 defibrillator/monitor Service Manual provides detailed technical information to support ;ervice and repair by qualified service personnel.

PRODUCT RECYCLING INFORMATION

Recycle the defibrillator and its accessories at the end of their useful life.

Recycling Assistance

The defibrillator and its accessories should be recycled according to national and local regulations. Contact your local Medtronic representative for assistance.

Preparation

The device should be clean and contaminant-free prior to being recycled.

Recycling of Disposable Electrodes

After using disposable electrodes, follow your local clinical procedures for recycling.

Packaging

Packaging should be recycled according to national and local regulations.

WARRANTY

Refer to the warranty statement included in the accessory kit shipped with this product. For duplicate copies, contact your local Medtronic representative. In the USA, call 1.800.442.1142. Outside the USA, contact your local Medtronic representative.

Using defibrillation electrodes, adapter devices, or other parts and supplies from sources other than Medtronic is not recommended. Medtronic has no information regarding the performance or effectiveness of its LIFEPAK defibrillators if they are used in conjunction with defibrillation electrodes or other parts and supplies from other sources. If device failure is attributable to defibrillation electrodes or other parts or supplies not manufactured by Medtronic, this may void the warranty.

ACCESSORIES, SUPPLIES, AND TRAINING TOOLS

Accessories, supplies, and training tools for the LIFEPAK 20 defibrillator/monitor are listed in Table 7-3. For information about ordering, contact your local Medtronic representative. In the USA, call 1.800.442.1142. Outside the USA, contact your local Medtronic representative.

Table 7-3 Accessories, Supplies, and Training Tools

Description	Part Number
Therapy Accessories	
QUIK-COMBO therapy cable	3006570
QUIK-COMBO pacing/defibrillation/ECG electrodes (EDGE System™)	3200496-01 (IEC)
Pediatric QUIK-COMBO RTS pacing/defibrillation/ECG electrodes (EDGE System)	3010107
QUIK-COMBO pacing/defibrillation/ECG electrodes with REDI-PAK (EDGE System) preconnect system	3202674
QUIK-COMBO RTS (radiotransparent system) pacing/defibrillation/ECG electrodes International	3010188-009
QUIK-COMBO pacing/defibrillation/ECG electrodes LLW (EDGE System) International	3008826
FAST-PATCH disposable defibrillation/ECG electrodes (EDGE System)	3010188-013
FAST-PATCH defibrillation adapter cable .6 m (2 ft)	3011030
Standard paddle set	3200936
Posterior paddle (for use with LIFEPAK 12 standard paddles 3006228)	802461
External sterilizable paddles	3009166
nternal handles with discharge control	3010901
nternal paddles	805355
Maintenance Accessories	
Defibrillator Checker	3011412
Medtronic Test Plug	3201673

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Table 7-3 Accessories, Supplies, and Training Tools (Continued)

Description	Part Number
SpO2 Accessories	
Disposable Adhesive Sensors	
LNOP Adt, 20/box Adult SpO2 sensor	3201655-005
LNOP Pdt, 20/box Pediatric 10-50 Kg SpO2 sensor	3201655-006
LNOP Neo, 20/box Neonatal <10 Kg SpO2 sensor	3201655-007
LNOP NeoPt, 20/box Neonatal <1 Kg SpO2 sensor	3201655-008
Reusable Sensor	
LNOP DCI, Adult SpO2 sensor	3201655-003
LNOP DCIP, Pediatric SpO2 sensor	3201655-004
Extension Cables	
PC04, 1/box, Patient cable 1.2 m (4 ft)	3201655-000
PC08, 1/box, Patient cable 2.4 m (8 ft)	3201655-001
PC12, 1/box, Patient cable 3.6 m (12 ft)	3201655-002
Other ECG Accessories	
3-lead ECG cable	3006218-02
5-lead ECG cable	3200496-00 (AHA)
QUIK-COMBO pacing/defibrillation/ECG electrodes (EDGE System)	3200496-01 (IEC)
LIFE•PATCH® ECG electrodes	800139
Data Management Software and Accessories	
CODE-STAT Suite Medical Informatics System	3011520
IrDA adapter for serial connection	3202608-001
IrDA adapter for USB connection	3202608-000
Other Accessories	
Docking Station	3201551
Accessory Holder	3202446
Supplies	
Recorder paper, 50 mm	804700
DERMA JEL® electrode gel	9-10236
Other	
Transport Configuration Cable	3202447
Training Tools	
QUIK-COMBO 3-lead simulator	806223
QUIK-COMBO 12-lead simulator	806395
QUIK-COMBO pacing/defibrillation/ECG training electrodes	3005903
QUIK-COMBO training electrodes cable (extension wire)	3004474
QUIK-COMBO Test Post Adapter	3005302-00
FAST-PATCH Therapy Cable Tester	805550-02
Patient simulator (for use with FAST-PATCH defibrillation adapter cable)	803499

Table 7-3 Accessories, Supplies, and Training Tools (Continued)

Description	Part Number
FAST-PATCH Training Electrodes	805565-01
FAST-PATCH Training Electrode Cable	803177-06
Literature:	
LIFEPAK 20 Defibrillator/Monitor Operating Instructions	3200750
LIFEPAK 20 Defibrillator/Monitor Service Manual	3202007
LIFEPAK 20 Defibrillator/Monitor Inservice Video (AED)	3202372
LIFEPAK 20 Defibrillator/Monitor Inservice Video (Manual)	3202373
Noninvasive Pacing: What You Should Know booklet	805074
Defibrillation: What You Should Know booklet	805662

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DEFINING SETUP OPTIONS

This section describes how to define setup options for the LIFEPAK 20 defibrillator/monitor.

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Set Passcode Setup Menu	8-10
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SETUP OPTIONS

Setup options allow you to define operating features for the LIFEPAK 20 defibrillator/monitor such as device identification numbers and default settings. Table 8-1 through Table 8-18 list all setup options along with the factory default settings.

Print Configurations Before Service or Repair

If the defibrillator receives service or repair that affects the internal memory components, such as replacement of the main printed circuit board, any changes previously made to the option definitions may be lost from memory. Before allowing service or repair, be sure to print the current user setup defaults so the customized definitions may be reentered after service or repair. (Refer to Print Defaults, page 8-10.)

Passcode Security

To prevent unauthorized access, a security passcode is required for access to the Setup menu and service mode (refer to page 8-10). The LIFEPAK 20 defibrillator/monitor allows you to change both of these passcodes. The passcode definition is part of the device identification option.

Note: To use the defibrillator with any new settings, you must turn the defibrillator off and on again.

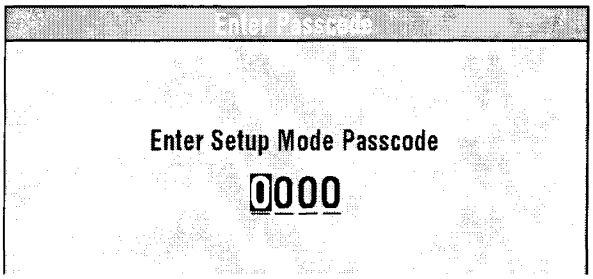
WARNING!

Possible ineffective energy delivery.

Service mode is for authorized personnel only. Improper use of service mode may inappropriately alter the device's configuration and may change energy output levels. Contact service personnel for assistance or information about device configuration.

ENTERING SETUP OPTIONS

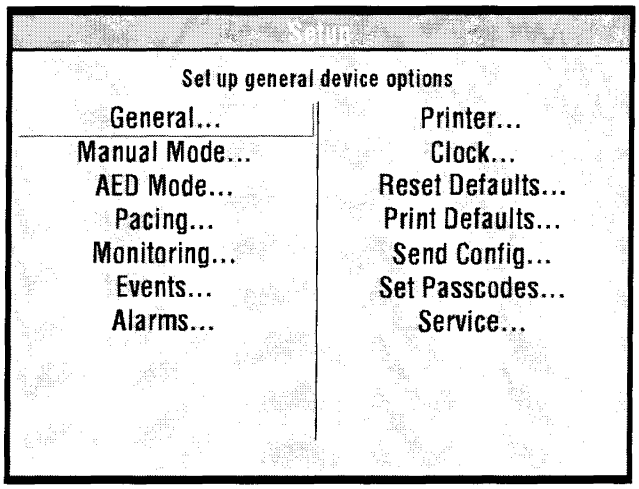
To enter the SETUP menu:



1. Press ON while holding down OPTIONS and EVENT. Continue to hold these controls down until the passcode screen appears.
2. Enter the passcode by scrolling through the digits in the highlighted fields.
3. Select the digit. The digit changes to a dot to protect the passcode. If you enter the correct digit, the next number in line highlights automatically.

   When you have entered the correct passcode, the setup overlay appears. If you enter the passcode incorrectly, the message *PASSCODE INCORRECT - TRY AGAIN* appears in the status message area. You have three chances to enter the passcode correctly. Turn the power off and on to start again.

Pressing HOME SCREEN after selecting a menu item returns you to the Setup screen.



Setup screen

GENERAL SETUP MENU

The General Setup menu allows you to define general purpose settings. When you select a menu item, the screen displays a help message. The options in bold are factory default settings.

Table 8-1 General Setup Menu

Menu Item	Help Message	Options
LANGUAGE	Language used for all messages and prompts	Options are: **ENGLISH**, FRENCH, GERMAN, SPANISH, SWEDISH, ITALIAN, DUTCH, FINNISH, DANISH, NORWEGIAN, POLISH, PORTUGUESE, BRAZILIAN, JAPANESE, and CHINESE MANDARIN.
CODE SUMMARY	CODE SUMMARY Format	Options are: SHORT and **MEDIUM** (refer to page 6-2).
SITE NUMBER	Site ID Number	Prints on reports. **0**-9, A-Z available. Maximum 25 digits.
DEVICE NUMBER	Device ID Number	Prints on reports. **0**-9, A-Z available. Maximum 25 digits.
AUTO LOG	Auto vital sign event capture every 5 minutes	**ON**: Vital sign data entered into event/vital sign log every 5 minutes. OFF: Vital sign entered only when events occur.
LINE FILTER	Line filter center frequency	50 or **60** Hz.
TIMEOUT SPEED	Delay before a menu is dismissed	Time that menus stay on screen (**30**, 10, or 5 seconds). (Pacing and Transmit menus are fixed at 30 seconds.)

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Table 8-1 General Setup Menu (Continued)

Menu Item	Help Message	Options
AC LOSS ALERT	A series of warning beeps if the device is off and not connected to ac power.	Options are: 5, **15**, or 30 minutes, or never alert.
PREVIOUS PAGE		Go back to previous page.

MANUAL MODE SETUP MENU

The Manual Mode Setup menu allows you to define defibrillation and synchronized cardioversion settings. When you select a menu item, the screen displays a help message. The options in bold are factory default settings.

Table 8-2 Manual Mode Setup Menu

Menu Item	Help Message	Options
SYNC	Set up sync defaults	Refer to Table 8-3.
PADDLES DEFAULT	Default energy for paddles or QUIK-COMBO™ electrodes	Power-on energy setting for standard paddles and therapy electrodes: 2, 5, 10, 50, 100, 125, 150, 175, **200**, 300 (joules), or Energy Protocol.
ENERGY PROTOCOL...	Energies for energy protocol	Refer to Table 8-4.
INTERNAL DEFAULT	Default energy for internal paddles	Power-on energy setting for internal paddles: 2, 5, **10**, 20, 30, or 50.
VOICE PROMPTS	Voice prompts active in manual mode	**ON**: Voice prompts active. OFF: Voice prompts inactive.
SHOCK TONE	Tone when defibrillator is fully charged	**ON**: A tone sounds. OFF: No tone.
MANUAL ACCESS	Means for accessing manual mode	**DIRECT**: No restrictions to manual mode. CONFIRMED: Confirmation required to gain manual access. PASSCODE: Passcode required to enter manual mode.
SET PASSCODE...	Passcode required to enter manual mode	If configured for passcode access: None: Default passcode enabled. New: User-defined 4-digit code enabled.

Table 8-3 Synchronization Defaults

Menu Item	Help Message	Options
SYNC AFTER SHOCK	Resume sync after energy transfer	**ON**: Defibrillator returns to synchronous mode after energy transfer. OFF: Defibrillator returns to asynchronous mode.
REMOTE SYNC	Allow sync with remote monitor	ON: Remote synchronization active. **OFF**: Remote synchronization inactive.

Table 8-4 Manual Mode Energy Protocol Setup Menu

Menu Item	Help Message	Options
PRESET PROTOCOL	Select preset energy protocol	Full range, low energy, pediatric.
ENERGY 1	Select energy level for shock 1	Full range: 100, 125, 150, 175, **200.** Pediatric: 2, 3, 4, **5**, 6, 7, 8, 9, 10, 15, 20, 30, 50, 70, 100.
ENERGY 2*	Select energy level for shock 2	Full range: All of energy level 1 and 225, 250, 275, **300**. Pediatric: Same as energy level 1.
ENERGY 3*	Select energy level for shock 3	Full range: All of energy level 2 and 325, **360**. Pediatric: 2, 3, 4, 5, 6, 7, 8, 9, **10**, 15, 20, 30, 50, 70, 100, 125, 150

*ENERGY 2 cannot be less than ENERGY 1. ENERGY 3 cannot be less than ENERGY 2.

To activate, select Energy Protocol in the Paddle Default menu. Auto energy sequences are disabled if you press the ENERGY SELECT control or change to or from AED mode during use.

AED MODE SETUP MENU

The AED Mode Setup menu allows you to define automated external defibrillator (AED) settings. When you select a menu item, the screen displays a help message describing the option. The options in bold are factory default settings.

Table 8-5 AED Mode Setup Menu

Menu Item	Help Message	Options
ENERGY PROTOCOL ...	Sequence of defibrillation energies	Refer to Table 8-6.
VOICE PROMPTS	Voice prompts on in AED Mode	**ON**: Voice prompt active. OFF: Voice prompt inactive.
AUTO ANALYZE	Automatically analyzes after shock	ON: Auto analyze active. **OFF**: Auto analyze inactive.
MOTION DETECTION	Alert when motion is detected?	ON or **OFF**.
ECG DISPLAY	Display Patient ECG	**ON** or OFF.
CPR TIME 1	Perform CPR for selected interval after 3 shocks	OFF, 15, 30, 45, **60**, 90, 120, 180 SECONDS, or 30 MINUTES.
CPR TIME 2	Perform CPR for selected interval after *NO SHOCK ADVISED**	OFF, 15, 30, 45, **60**, 90, 120, 180 SECONDS, or 30 MINUTES.
CPSS DURING CPR	Performs CPSS during CPR time	**ON** or OFF
FLEXIBLE PROTOCOLS	Repeat previous energy after NO SHOCK ADVISED	**ON** or OFF.

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*When a NO SHOCK ADVISED message appears immediately after a shock, the CPR period is the same as CPR Time 1. For all selections except OFF, the device prompts you to perform CPR and the screen displays a countdown timer.

Table 8-6 AED Mode Energy Protocol Setup Menu

Menu Item	Help Message	Options
PRESET PROTOCOLS	Select a preset energy protocol	Full range—Outside the USA: ENERGY 1: 150, 175, **200**. ENERGY 2: 150, 175, 200, 225, 250, 275, **300**. ENERGY 3: 150, 175, 200, 225, 250, 275, 300, 325, **360**. Full range—Inside the USA: ENERGY 1: **200**. ENERGY 2: 200, 225, 250, 275, **300**. ENERGY 3: 200, 225, 250, 275, 300, 325, **360**. **Note:** ENERGY 2 cannot be less than ENERGY 1. ENERGY 3 cannot be less than ENERGY 2.

PACING SETUP MENU

The Pacing Setup menu allows you to define noninvasive pacemaker settings. When you select a menu tem, the screen displays a help message. The options in bold are factory default settings.

Table 8-7 Pacing Setup Menu

Menu Item	Help Message	Options
RATE	Default pacing rate	40–170, **60**.
CURRENT	Default pacing current	**0**–200 mA.
MODE	Default pacing mode	**DEMAND** or NONDEMAND.
INTERNAL PACER	Detect internal pacemaker and print arrows	DETECTION OFF or **DETECTION ON**.

MONITORING MENU

Use the Monitoring menu to define settings for the ECG and SpO2 monitoring. When you select a menu tem, the screen displays a help message. The options in bold are factory default settings.

Table 8-8 Monitoring Menu

Menu Item	Help Message	Options
CHANNELS...	Set up default channel waveforms	Refer to Table 8-9.
CONTINUOUS ECG	Continuously store ECG waveform	ON or **OFF**.
SPO2 TONE	SpO2 pulse tone	ON or **OFF**.

Channels Setup Menu

To define the default set and up to five optional waveform sets for Channels 1 and 2, select an item from the Channels Setup menu.

Table 8-9 Channels Setup Menu

Menu Item	Help Message	Options
Default SET	Select default waveform set	**Set 1**, Set 2, Set 3, Set 4, or Set 5.
SET 1	Select channel waveforms for Set 1	Refer to Table 8-10.
SET 2	Select channel waveforms for Set 2	Refer to Table 8-10.
SET 3	Select channel waveforms for Set 3	Refer to Table 8-10.
SET 4	Select channel waveforms for Set 4	Refer to Table 8-10.
SET 5	Select channel waveforms for Set 5	Refer to Table 8-10.

Waveform Sets Setup Menu

Table 8-10 Waveform Sets Setup Menu

Menu Item	Help Message	Options*
CHANNEL 1	Select waveform for channel 1	Paddles, ECG Lead I, ECG **Lead II**, ECG Lead III, (AVR, AVL, AVF, C)
CHANNEL 2	Select waveform for channel 2	**NONE**, Cascading ECG, paddles, ECG Lead I, ECG Lead II, ECG Lead III, (AVR, AVL, AVF, C), SpO2

*Only available leads appear as options.

EVENTS SETUP MENU

Jse the Events Setup menu to configure or create user-annotated events. When you select a menu tem, the screen displays a help message.

Table 8-11 Events Setup Menu

Menu Item	Help Message	Options
EVENTS PAGE 1	Select events for Page 1	Select events 2 to 9 from a preset list.
EVENTS PAGE 2	Select events for Page 2	Select events 10 to 18 from a preset list.
CUSTOM EVENTS	Create custom events to use in event screen	Create up to 16 event names to include in the preset list. **Note:** Resetting to defaults will delete the custom list.

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ALARMS SETUP MENU

The Alarms Setup menu allows you to define alarms and set the alarm volume level. When you select a menu item, the screen displays a help message. The options in bold are factory default settings.

Table 8-12 Alarms Setup Menu

Menu Item	Help Message	Options
VOLUME	Set volume for alarms, tones, and voice prompts	Select volume level from gradient display. The minimum setting reduces but does not silence alarms.
ALARMS	Enable alarms at power up	ON: Enables alarms for Heart Rate and SpO2, whenever defibrillator power is turned on. **OFF**: Alarms available through ALARMS button.
VF/VT ALARM	Alarms when VF or VT detected	ON: Enables VF/VT alarm whenever defibrillator power is turned on. **OFF**: VF/VT alarm available through ALARMS button.

PRINTER SETUP MENU

The Printer Setup menu allows you to define automatic event printing and ECG frequency response. When you select a menu item, the screen displays a help message. The options in bold are factory default settings.

Table 8-13 Printer Setup Menu

Menu Item	Help Message	Options
AUTO PRINT	Specify Auto Print Event	See Table 8-14.
ECG MODE	Default ECG frequency response	**Monitor** or Diagnostic
MONITOR MODE	Default monitor frequency response for printer and display	**1–30 Hz** or .5–40 Hz.
DIAGNOSTIC MODE	Default diagnostic frequency response for printer	**.05–40 Hz** or .05–150 Hz.
ALARM EVENTS	Print waveforms with alarm events and print with CODE SUMMARY report	**ON** or OFF.
EVENT WAVEFORMS	Print waveforms with user-entered events and print with CODE SUMMARY report	**ON** or OFF.

Auto Print Setup Menu

Table 8-14 Auto Print Setup Menus

Menu Item	Help Message	Options
DEFIBRILLATION	Auto print defibrillation events	**ON** or OFF.
PACING	Auto print pacing events	ON or **OFF**.
CHECK PATIENT	Auto print check patient events	ON or **OFF**.
SAS	Auto print SAS events	ON or **OFF**.
PATIENT ALARMS	Auto print patient alarms	ON or **OFF**.
EVENTS	Auto print operator annotated events	ON or **OFF**.
INITIAL RHYTHM	Auto print initial rhythm	ON or **OFF**.
SELF TEST	Auto print self test result	ON or **OFF**.

CLOCK SETUP MENU

Use the Clock Setup menu to define settings for the time to be displayed. When you select a menu item, the screen displays a help message. The options in bold are factory default settings.

Table 8-15 Clock Setup Menu

Menu Item	Help Message	Options
DATE/TIME	Set current date and time	Current date will be active next time defibrillator power is turned on.
CLOCK MODE	Real or elapsed time on display	**REAL TIME** or ELAPSED TIME.
DST	Daylight savings time	**ON** or OFF.
TIME ZONE	Select time zone for this device	**NONE**, 74 time zone settings.

RESET DEFAULTS SETUP MENU

Use the Reset Defaults menu to configure the device for all factory default settings.

Table 8-16 Reset Defaults Setup Menu

Menu Item	Help Message	Options
CANCEL	Cancel and return to Setup screen	Cancels reset operation.
RESET	Reset to factory configuration settings	Resets setup parameters to the factory default settings, except for transmission sites, output ports, initialization strings, and the maintenance interval, which remain unchanged.

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PRINT DEFAULTS

Use the Print Defaults menu to print the current device configuration setup.

SEND CONFIGURATION SETUP MENU

Use the Send Configuration Setup menu to transfer the setup configuration in one device to overwrite the setup configuration in another device. You can send configurations between devices with different features because all devices have identical setup menus, regardless of features.

To send the configuration from one device to another:

1 Connect the Transport Configuration Cable (PN 3202447) to the system connector on both defibrillators.
2 Turn on the sending defibrillator and enter setup mode (see page 8-2).
3 Select the SEND CONFIG... menu option.
4 Turn on the receiving device.
5 Select SEND on the sending defibrillator and follow the screen prompts.

Table 8-17 Send Configuration Setup Menu

Menu Item	Help Message	Options
SEND	Send device configuration to another device.	Connect devices with a cable (PN 3202447), display this screen on both devices, then select SEND.
PREVIOUS PAGE	Go back to previous page.	Cancels the operation.

SET PASSCODE SETUP MENU

Use the Set Passcode menu to change the factory default passcode of 0000 to some other number. If you lose the setup passcode, you will have to contact the factory for assistance.

Table 8-18 Set Passcode Setup Menu

Menu Item	Help Message	Options
SETUP MODE	(The current passcode appears.) Set passcode to enter setup mode	Rotate the speed dial to select digits.
ARCHIVES ACCESS	Select passcode access for archives mode	**NO PASSCODE**, ARCHIVES ONLY, DELETE ONLY, ARCHIVES/DELETE.
ARCHIVES MODE	Set passcode to enter archives mode.	Rotate the speed dial to select digits.
DELETE	Set passcode to delete records in archives mode.	Rotate the speed dial to select digits.

SERVICE MODE

The service mode contains tests and logs intended for service personnel. For specific information concerning access to the service mode, refer to the LIFEPAK 20 Defibrillator/Monitor Service Manual.

APPENDIX A
SPECIFICATIONS AND PERFORMANCE CHARACTERISTICS

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All specifications are at 20°C (68°F) unless otherwise stated.

GENERAL

The LIFEPAK 20 defibrillator/monitor has seven main operating modes:

Manual Mode	Provides normal operating capability for ALS users
AED Mode	Provides normal operating capability for BLS users
Archive Mode	Allows operator to print, edit or delete previous patient records
Setup Mode	Allows operator to configure the instrument
Service Mode	Allows operator to execute device diagnostic tests and calibrations
Inservice Mode	Provides simulated waveforms for demonstration purposes
Auto Test Mode	Provides daily automatic tests of critical circuits

POWER

AC Powered	90-132 VAC 50/60 HZ, 198-264 VAC 50/60 HZ, total power draw less than 75 Watts
Internal Battery Backup	Battery charges while device operates from AC Power Typical battery charge time of less than 2 hours when device is powered off and AC power is applied.

Operating Time

A new fully charged internal backup battery will provide the following prior to shutdown,

	---total--- Min.	---after low battery--- Min.
Monitoring (minutes):	120	5
Monitoring with no SpO2 (minutes)	135	5
Defibrillation (360 J discharges):	90	3
Monitoring Plus Pacing (minutes at 100 mA, 60 ppm):	70	2

Low Battery Indication	Low battery message in status area and warning tone sounds.
Warmstart	With inadvertent loss of power (less than 30 seconds) device retains settings.
A Service Indicator	When Error Detected

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PHYSICAL CHARACTERISTICS

Weight	Basic defibrillator/monitor with Hard Wired Hard Paddles: 6.17 kg (13.6 lb)
	Fully featured defibrillator/monitor (Pacing, SpO2, and door) without paper or cables: 5.58 kg (12.3 lb)
Size (maximum)	
Height	21.3 cm (8.4 in.)
Width	26.2 cm (10.3 in.)
Depth	26.2 cm (10.3 in.)

DISPLAY

Size (active viewing area)	115.18 mm (4.53 in.) wide x 86.38 mm (3.4 in.) high
Display Type	320 dot x 240 dot color active or passive (base unit only) LCD
	User selectable display contrast for LCD (passive only)
	Displays a minimum of 4 seconds of ECG and alphanumerics for values, device instructions, or prompts
	Option to display one additional waveform
	Waveform display sweep speed: 25mm/sec for ECG

DATA MANAGEMENT

	The device captures and stores patient data, events (including waveforms and annotations), and continuous ECG waveform records in internal memory
	The user can select and print reports
Report Types	Two format types of CODE SUMMARY critical event record (short and medium)
	• Initial ECG (except short format)
	• Auto vital sign measurements every 5 minutes
Memory Capacity	Two full-capacity patient records that include CODE SUMMARY critical event records - up to 100 single waveform events

MONITOR

ECG	ECG is monitored via several cable arrangements. A 3-wire cable is used for 3-lead ECG monitoring. A 5-wire cable is used for 3-lead ECG plus AVR, AVL, AVF, and C. Standard paddles or therapy electrodes (QUIK-COMBO pacing/defibrillation/ECG electrodes or FAST-PATCH disposable defibrillation/ECG electrodes) are used for paddles lead monitoring. Compatible with LIFEPAK 12 ECG and Therapy Cables.
Lead Selection	Leads I, II, III (3-wire ECG cable)
	Leads I, II, III, AVR, AVL, AVF, and C acquired simultaneously (5-wire ECG cable)
ECG Size	4, 3, 2.5, 2, 1.5, 1, 0.5, 0.25 cm/mV
Heart Rate Display	20–300 bpm digital display
	Out of range indication: Display symbol "---"
	Heart symbol flashes for each QRS detection
Continuous Patient Surveillance System (CPSS)	In AED mode, while Shock Advisory System is not active, CPSS monitors the patient, via QUIK-COMBO paddles or Lead II ECG, for potentially shockable rhythms.
Voice Prompts	Used for selected warnings and alarms (configurable on/off).
Analog ECG Output	1 V/mV x 1.0 gain <30 msec delay
Common Mode Rejection	95 dB at 50/60 Hz
SpO2	Masimo sensors
Saturation range	1 to 100%
Saturation Accuracy	70–100 % (0–69 % unspecified)
Adults/Pediatrics	±2 digits (during no motion conditions) ±3 digits (during motion conditions)
Neonates	±3 digits (during no motion conditions) ±3 digits (during motion conditions)
Dynamic signal strength bar graph	
Pulse tone at the onset of the pleth waveform	
SpO2 Update Averaging Rate	User selectable 4, 8, 12 or 16 seconds
SpO2 measurement	Functional SpO2 values are displayed and stored
Pulse rate range	25 to 240 pulses per minute
Pulse rate accuracy	
Adults/Pediatrics/Neonates	±3 digits (during no motion conditions) ±5 digits (during motion conditions)
SpO2 waveform with autogain control	
Alarms	
Quick Set	Activates alarms for all parameters
VF/VT Alarm	Activates continuous CPSS monitoring in Manual Mode

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PRINTER

	Prints continuous strips of the displayed patient information
Paper Size	50 mm (2.0 in.)
Print Speed	Continuous ECG 25 mm/sec ±5% (measured in accordance with AAMI EC-11, 4.2.5.2)
	25 mm/sec print speed for CODE SUMMARY Reports
Delay	8 seconds
Autoprint	Waveform events print automatically (user configurable)

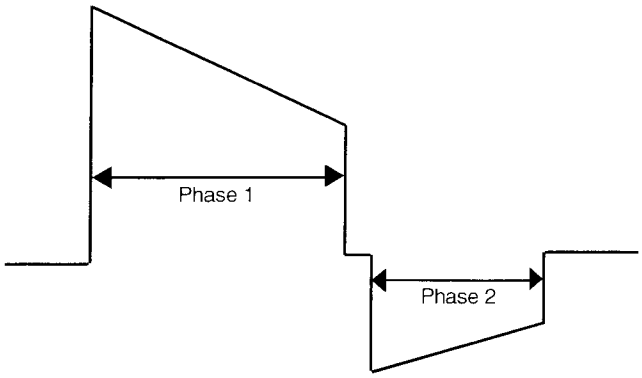
FREQUENCY RESPONSE

Diagnostic Frequency Response	0.05 to 150 Hz or 0.05 to 40 Hz (user configurable)
Monitor Frequency Response	0.67 to 40 Hz or 1 to 30 Hz (user configurable)
Paddles Frequency Response	2.5 to 30 Hz
Analog ECG Output Frequency Response	0.67 to 32 Hz (except 2.5 to 30 Hz for Paddles ECG)

DEFIBRILLATOR

Manual

Energy Select	2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 30, 50, 70, 100, 125, 150, 175, 200, 225, 250, 275, 300, 325, and 360 J or one of two user configurable protocols of three sequential shock levels
Full Range	100–200, 100–300, 100–360 J
Pediatric	2–100, 2–100, 2–150 J
Charge Time	Charge time to 200 J in less than 4 seconds with fully charged battery Charge time to 360 J in less than 7 seconds with fully charged battery Charge time to 360 J in less than 10 seconds while not in low battery operations
Synchronous Cardioversion	Energy transfer begins within 60 msec of the QRS peak Energy transfer begins with 25 msec of the External Sync Pulse External Sync Pulse: 0-5V (TTL Level) Pulse, active High, > 5 msec in duration, no closer than 200 msec apart and no further than 1 sec apart
Waveform	Biphasic Truncated Exponential
	The following specifications apply from 25–200Ω, unless otherwise specified.
	Energy Accuracy: ±1 J or 10% of setting, whichever is greater, into 50Ω: ±2 J or 15% of setting, whichever is greater, into any impedance from 25–100Ω.
	Voltage Compensation: Active when disposable therapy electrodes are attached. Energy output within ±5% or ±1 J, whichever is greater, of 50Ω value limited to the available energy which results in the delivery of 360 J into 50Ω.



Patient Impedance (Ω)	Phase 1 Duration (msec) Min	Max	Phase 2 Duration (msec) Min	Max	Tilt (%) Nominal
25	5.1	6.0	3.4	4.0	77.5
50	6.8	7.9	4.5	5.3	65.8
100	8.7	10.6	5.8	7.1	52.6
125	9.5	11.2	6.3	7.4	47.8

Note: Tilt is the amount of slope in waveform, expressed as the amount the current or voltage drops before truncation. A 100% tilt waveform would be termed nontruncated.

Paddle Options	QUIK-COMBO pacing/defibrillation/ECG electrodes (standard)
	FAST-PATCH disposable defibrillation/ECG electrodes (optional)
	Standard Paddles (optional)
	Internal Handles with discharge control (optional)
	External Sterilizable Paddle (optional)
Cable Length	2.4 m (8 ft) long QUIK-COMBO cable (not including electrode assembly)

AED Mode

Shock Advisory System (SAS)	ECG analysis system that advises the operator if the algorithm detects a shockable or nonshockable ECG rhythm. SAS acquires ECG via therapy electrodes only.
Shock Ready Time (AED Mode)	Using a fully charged battery at normal room temperature, the device is ready to shock within 16 seconds of power on, if the initial rhythm finding is SHOCK ADVISED.
Output Energy	One user configurable protocol with three sequential shock levels
Full Range*	150–200, 150–300, 150–360 J

*Energy selections of 150 and 175 J are available in "outside the USA" configurations only

PACER

Pacing Mode	Demand or non-demand Rate and current defaults (user configurable)
Pacing Rate	40 to 170 ppm
Rate Accuracy	±1.5% over entire range

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Output Waveform	Monophasic, amplitude stable to ±5% relative to leading edge for currents greater than or equal to 40 mA, Duration 20 ±1 msec, Rise/Fall times <= 1 msec [10-90% levels]
Output Current	0 to 200 mA
Pause	Pacing pulse frequency reduced by a factor of 4 when activated
Refractory Period	200 to 300 msec ±3% (function of rate)

ENVIRONMENTAL

Temperature, Operating	5° to 45°C (41° to 113°F)
Temperature, Non-Operating	-20° to 60°C (-4° to 140°F) except therapy electrodes
Relative Humidity, Operating	5 to 95%, non-condensing
Atmospheric Pressure, Operating	Ambient to 429 mmHg (0 to 4572 meters) (0 to 15,000 ft)
Water Resistance, Operating (without accessories except for ECG Cable and Hard Paddles)	IPX1 (spillage) per IEC 60601-1 clause 44.6
EMC	Emissions: MIL-STD-461D, RE101; IEC 60601-1-2 (1993) subclause 36.201.1 Susceptibility: MIL-STD-461D, CS114, RS101; IEC 60601-1-2 (1993) subclause 36.202
Shock (drop)	1 drop on each side from 45.7 cm (18 in.) onto a steel surface
Vibration	MIL-STD-810E Method 514.4, Cat 1

CHARACTERISTIC

Respiration, Leads Off Sensing, Noise Cancellation Current, and Voltage	The ECG leads off function uses ac current for sensing leads off, the disposable defibrillation electrodes use ac current for leads off, and the ECG leads use a noise cancellation signal which ranges from dc to approximately 5k Hz. The amplitude of these signals conforms to AAMI EC-11 3.2.10 and EC-13 3.2.5.
Heart Rate Averaging Method	The heart rate average is formed by a weighted average of approximately 8 seconds duration. When the input rate is trending rapidly, the rate meter will track more quickly. See heart rate response time disclosure. The display update interval is every heartbeat or every 2 seconds, whichever is shorter.
Heart Rate Response Time	Heart rate meter response time: For an 80 to 120 bpm step change, the response time is 5.5 seconds average with a range of 4.9 to 6.2 seconds when tested per AAMI 4.1.2.1 f. For an 80 to 40 bpm step change, the response time is 5.6 seconds with a range of 5.0 to 6.4 seconds.
Heart Rate With Irregular Rhythm	All complexes are detected. The rate meter output can range from the heart rate associated with the shortest R-R interval to the heart rate associated with the longest R-R interval. When present, intermediate length R-R intervals are favored as the basis for the rate.

CHARACTERISTIC	
Heart Rate Alarm Time	In five trials for a 1 mV, 206 bpm tachycardia, the average detection time was 7.1 seconds. The maximum detection time was 7.9 seconds. The minimum time was 5.6 seconds. For a test signal half as large, the average was 6.1 seconds, the maximum was 6.4, and the minimum was 5.7. In this case the device sensitivity was increased to 5 mV/cm. For a test signal twice as large, the average was 5.7 seconds, the maximum was 6.3, and the minimum was 5.1. In five trials for a 2 mV, 195 bpm tachycardia, the average detection time was 6.2 seconds. The maximum detection time was 7.1 seconds. The minimum time was 5.8 seconds. For a test signal half as large, the average was 6.0 seconds, the maximum was 6.7, and the minimum was 5.4. In this case the device sensitivity was increased to 5 mV/cm. For a test signal twice as large, the average was 6.0 seconds, the maximum was 6.4, and the minimum was 5.8.
Accuracy Of Signal Reproduction	The device is a digital sampled data system. It meets requirements for both test methods for diagnostic frequency response described in EC11 section 3.2.7.2.
Audible Alarms	This is a standalone device. All alarm tones are internal to the biphasic LIFEPAK 20 defibrillator/monitor. Alarm violations are manifest by tones, voice prompts, and visual indications. Alarm manifestation occurs within 1 second after a displayed parameter violates its alarm limit. User selectable alarm volume adjustment is provided. This adjustment does not allow alarm volume to attain/reach a zero level. SAS tones reinforce SAS messages provided on the product display. The following identifies the tone assignments for each type of alarm: • The priority 1 tone is used to alert the user to the possibility of imminent death. This tone is a 440 Hz and 880 Hz alternating tone with a 50% duty cycle and a 4 Hz alternation frequency. This tone has a volume of 70±5 dB (A) as measured at a distance of 1 meter from the display. • The priority 2 tone is used to alert the user that a possible life-threatening condition exists. This tone is a continuous 698 Hz tone.

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CHARACTERISTIC	
	• The priority 3 tone is used to alert the user that an abnormal condition exists. Three beeps at 1046 Hz for 100 msec duration each with a 150 msec silence between the first and second and the second and third, followed by a 200 msec silence. • Priority 3 tones come in single and repeating types: for a single tone, the 3-beep sequence sounds only once. For a repeating tone, the 3-beep sequence sounds every 20 seconds. • The priority 4 tone is a momentary tone between 500 and 1500 Hz. Specific characteristics are: – QRS and Volume Setting Tone - 100 msec duration at 1397 Hz. – Key click - 4 msec duration at 1319 Hz. The alert tone shall consist of one set of two tones to precede voice prompts and to draw attention to the display. Specific characteristics shall be: • 1000 Hz square wave, 100 msec duration. • Silence, 100 msec duration. • Silence, 140 msec duration (when preceding a voice prompt). • Voice prompt, when used.
Visual Alarms	Alarms are indicated visually by: The violated parameter flashes in inverse video with a message in the status region of the display. These visual indications remain on the display until the alarm is corrected. Visual indication of alarms continue even when the tones have been silenced.
Alarm Silencing	If a violated parameter alarms, the tone may be silenced for two minutes by pressing the Alarms button. A preemptive alarm silence is provided with selectable settings of 2, 5, 10, and 15 minutes. Visual alarms remain on at all times.
VF/VT Alarm	Automatically monitors the patient's ECG rhythm for a potentially shockable rhythm using the Continuous Patient Surveillance System (CPSS). The VF/VT alarm requires that the patient's ECG be monitored in Lead II or Paddles lead using therapy electrodes. The VF/VT alarm will be suspended if pacing is enabled or Standard paddles are connected and Paddles is the displayed lead.
Energy Shunting	If the paddles input is connected in parallel with a second defibrillator, energy delivery to the patient is reduced by less than 10 percent.
Tall T-wave Rejection	T-waves that are 1 mV high are not detected by the monitor when the R-wave size is 1 mV and input rate is 80 ppm.

CHARACTERISTIC	
Charge Time	For battery-only operation (using a fully charged battery): The defibrillator charge time to 360 J is less than 10 seconds, following 15 full energy discharges, per IEC 601-2-4. For ac operation. The defibrillator charge time to 360 J is less than 10 seconds, at 90% of rated nominal Mains voltage, per IEC 601-2-4.
Displayed SpO2	The LIFEPAK 20 defibrillator/monitor is calibrated to display functional saturation, which is the standard for SpO2.

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APPENDIX B
CLINICAL SUMMARIES

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DEFIBRILLATION OF VENTRICULAR FIBRILLATION AND VENTRICULAR TACHYCARDIA

Background

Medtronic conducted a multi-centered, prospective, randomized and blinded clinical trial of biphasic truncated exponential (BTE) shocks and conventional monophasic damped sine wave (MDS) shocks. Specifically, the equivalence of 200J and 130J BTE shocks to 200J MDS shocks[1] was tested.

Methods

Ventricular fibrillation (VF) was induced in 115 patients during evaluation of implantable cardioverter defibrillator function and 39 patients during electrophysiologic evaluation of ventricular arrhythmias. After 19±10 seconds of VF, a customized defibrillator delivered an automatically randomized shock. Efficacy was based on success of this shock. To demonstrate equivalence of test shocks to control shocks, the 95% upper confidence limit of the difference in efficacy (95UCLD), control minus test, was required to be less than 10%.

Results

Ventricular Fibrillation

The efficacy of the 200J BTE shocks was demonstrated to be at least equivalent to the efficacy of 200J MDS shocks (95UCLD=2%). The difference in success rates of 200J MDS minus 200J BTE shocks was -10% (exact 95% confidence interval from -27% to 4%). The 130J BTE shocks were not demonstrated equivalent to 200J MDS shocks (95UCLD=22%). However, neither was their efficacy significantly lower than that of the 200J MDS shocks (statistical power limited by small sample sizes). For all shock types, hemodynamic parameters (oxygen saturation and systolic and diastolic blood pressure) were at or near their pre-induction levels by 30 seconds after successful shocks.

Shock	Ventricular Fibrillation 1st Shock Success	Exact 95% Confidence Interval
200J MDS	61/68 (90%)	80-96%
200J BTE	39/39 (100%)	91-100%
130J BTE	39/47 (83%)	69-92%

S.L. Higgins et al., "A comparison of biphasic and monophasic shocks for external defibrillation," *Prehospital Emergency Care*, 2000, 4(4):305-13.

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Ventricular Tachycardia

Seventy-two episodes of ventricular tachycardia (VT), induced in 62 patients, were treated with randomized shocks. High rates of conversion were observed with biphasic and monophasic shocks. Sample sizes were too small to statistically determine the relationship between success rates of the waveforms tested.

Shock	Ventricular Tachycardia 1st Shock Success	Exact 95% Confidence Interval
200J MDS	26/28 (93%)	77-99%
200J BTE	22/23 (96%)	78-100%
130J BTE	20/21 (95%)	76-100%

Conclusions

In this double-blinded study, the efficacy of the 200J BTE shocks was demonstrated to be at least equivalent to the efficacy of 200J MDS shocks for defibrillation of short duration, electrically-induced VF. However, the comparison of efficacy of 130J biphasic and 200J monophasic shocks for VF was inconclusive. All waveforms tested provided a high rate of termination of VT. The VT sample sizes were too small to statistically determine the relationship between VT success rates of the waveforms tested.

Compared to conventional shocks for VF, we found no positive or negative effect of biphasic shocks for VF on hemodynamic parameters following the defibrillating shock. It is possible that, compared to 200J monophasic shocks, 200J biphasic shocks will in some cases enable earlier termination of VF. Therefore, we conclude that biphasic shocks for VF delivered at conventional energy levels have the potential to improve outcome in resuscitation of patients with cardiac arrest.

EXTERNAL CARDIOVERSION OF ATRIAL FIBRILLATION

Overview

The performance of Medtronic's biphasic truncated exponential (BTE) waveform was compared to the conventional monophasic damped sine (MDS) waveform in an international, multi-center, prospective, randomized clinical study of adult patients undergoing elective cardioversion of atrial fibrillation (AF). A total of 80 patients were enrolled in the study and were treated with one or more study shocks. The primary dataset consisted of 72 enrolled patients confirmed to have been in AF. Data from seven patients with atrial flutter were analyzed separately. One patient who did not satisfy all protocol criteria was excluded from analysis.

Subjects were randomized to receive biphasic or monophasic shocks from LIFEPAK 12 defibrillator/monitors. Progressive shocks of 70, 100, 200 and 360 J of the assigned waveform, and a 360 J crossover shock of the other waveform, were delivered if AF persisted. Shocks were delivered using EDGE System QUIK-COMBO Pacing/Defibrillation/ECG electrodes applied in the standard anterior-lateral position. Successful cardioversion was defined as the confirmed removal of AF after delivery of a shock, as determined by ECG over-read by two cardiologists with no knowledge of the shock waveform. Patients rated skin pain on a scale from 0 to 8 after the procedure.

This study showed that these biphasic shocks provide higher efficacy for cardioversion of atrial fibrillation, requiring fewer shocks, 65% less current and 65% less energy to cardiovert atrial fibrillation. Patients undergoing elective cardioversion with the biphasic protocol, as compared to those receiving the monophasic protocol, reported significantly less post-procedure pain.

Objectives

The primary objective of the study was to compare the cumulative efficacy of biphasic and monophasic shocks of 200 J or less for cardioversion of atrial fibrillation. A triangular sequential design was used to test for a statistically significant difference between groups of patients treated with these two waveforms.

Secondary objectives included 1) providing an estimation of the dose response relationship for the two waveforms which would allow clinicians to make well-informed selections of energy doses for cardioversion with biphasic shocks and 2) comparing the pain experienced by patients following treatment with monophasic and biphasic shocks.

Results

Seventy-two of the patients enrolled were in atrial fibrillation and 7 were in atrial flutter. On average, patients had been in atrial fibrillation for 88 days, were 66 years old, weighed 81 kg and had 72 ohms of transthoracic impedance. Sixty-three percent were male and 46% had been previously cardioverted. There were no significant differences between the groups of patients treated with monophasic and biphasic shocks, either in these baseline characteristics or in left atrial dimension, cardiac medications or diagnosis.

The cumulative success rates for cardioversion of atrial fibrillation are presented in Table B-1 and Figure B-1. These data provide a reasonable estimate of the expected probability of cardioversion success for a single shock at any given energy level within the range studied. Energy and peak current delivered for all shocks at each energy setting are presented in Table B-2.

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Table B-1 Cumulative Success Rates and Crossover Results for Cardioversion of AF

Energy Setting	70 J	100 J	200 J	360 J	360 J Crossover Successes
MDS: n = 37	5.4%	19%	38%	86%	4 of 5 pts succeeded with 360 J BTE shock
BTE: n = 35	60%	80%	97%	97%	0 of 1 pts succeeded with 360 J MDS shock

Cumulative percentages of successes for cardioversion of AF with shocks of 200 J or less, the primary endpoint of the study, was significantly higher in the biphasic group than the monophasic group ($p<0.0001$). The observed cumulative percentage of successes at 360 J was also higher for biphasic shocks than for monophasic shocks, but did not attain statistical significance.

Table B-2 Energy Settings, Delivered Energy and Peak Current for Shocks Delivered to Patients in AF

Energy Setting	Number of Patients	Delivered Energy	Peak Current, Amps
Monophasic shocks			
70 J	37	73 ±3	21.0 ±3.5
100 J	35	105 ±4	24.6 ±4.3
200 J	30	209 ±7	34.6 ±5.9
360 J	23	376 ±13	46.8 ±8
360 J crossover shocks	1	380	44.7
Biphasic shocks*			
70 J	35	71 ±0	11.9 ±2.5
100 J	14	102 ±0	14.9 ±3.5
200 J	7	203 ±1	20.6 ±3.5
360 J	1	362	28.5
360 J crossover shocks	5	361 ±6	32.4 ±8.5

*Peak current and delivered energy are not available for two of the patients treated with biphasic shocks.

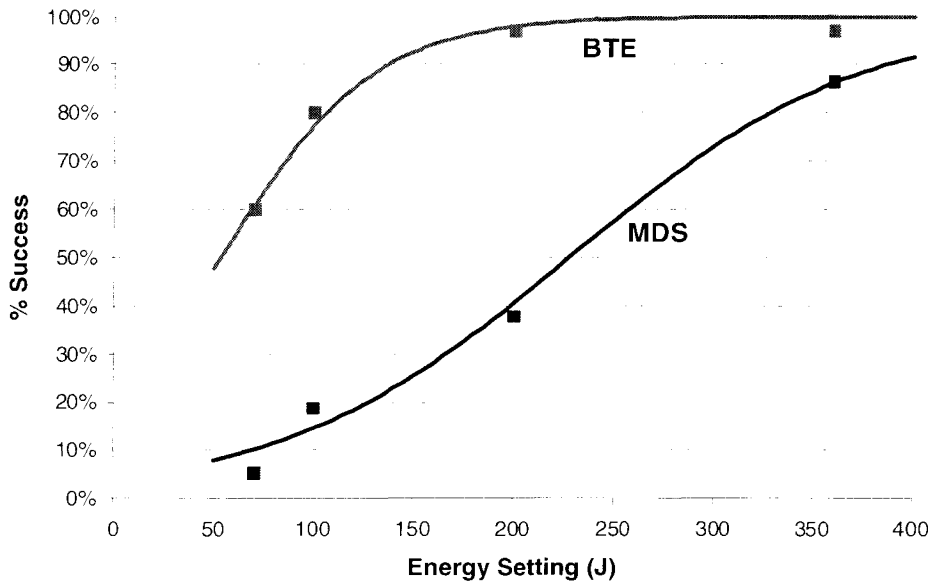

Figure B-1 Cumulative Shock Success for Cardioversion of Atrial Fibrillation with Monophasic (MDS) and Biphasic (BTE) Shocks: Observed Rates (■) Plotted with Estimated Dose Response Curves

Compared to monophasic shocks, biphasic shocks cardioverted atrial fibrillation with less peak current 14.0 ± 4.3 vs. 39.5 ± 11.2 A, p<0.0001), less energy (97 ± 47 vs. 278 ± 120 J, p<0.0001), fewer shocks 1.7 vs. 3.5 shocks, p < 0.0001) and less cumulative energy (146 ± 116 vs. 546 ± 265 J, p<0.0001). Patients treated with the biphasic protocol, as compared to those treated with the monophasic protocol, reported significantly less post-procedure pain just after (0.4 ± 0.9 vs. 2.5 ± 2.2, p<0.0001) and 24 hours after the procedure (0.2 ± 0.4 vs. 1.6 ± 2.0, p<0.0001).

All patients with atrial flutter were cardioverted with the first shock (70 J), whether that shock was monophasic (n=4) or biphasic (n=3).

Anterior-lateral electrode placement was used for treatment of most (96%) of the patients studied. Reports in the literature differ on whether anterior-posterior electrode placement provides better shock efficacy than anterior-lateral placement. If there is a benefit to anterior-posterior electrode placement, it may be possible to obtain modestly higher cardioversion success rates with both waveforms than those observed in this study. However, placement is not likely to affect the observed relationship *between* the efficacies of monophasic and biphasic waveforms.

Conclusions

The data demonstrate Medtronic's biphasic waveform is clinically superior to the conventional monophasic damped sine waveform for cardioversion of atrial fibrillation. Specifically, compared to monophasic shocks, biphasic shocks cardioverted atrial fibrillation with less peak current, less energy, fewer shocks and less cumulative energy. Patients undergoing elective cardioversion with the biphasic protocol, as compared to those receiving the monophasic protocol, reported significantly less post-procedure pain just after and 24 hours after the procedure. This may be due to fewer required shocks, less cumulative energy, less delivered peak current or other characteristics of this biphasic waveform.

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Guidance for Selection of Shock Energy

Biphasic waveform technology is an emerging standard in cardiac defibrillators. The study summarized here[1, 2], in addition to a small pilot study[3] and a prospective case series[4] of cardioversion of atrial fibrillation with Medtronic biphasic truncated exponential shocks, provide the best information available on which to base energy selections for cardioversion with this waveform.

For cardioversion of atrial fibrillation, the results of this study provide specific guidance for three possible strategies in selection of shock energy levels.

- To optimize for more rapid cardioversion and fewer shocks, select the same biphasic energy levels used previously with monophasic defibrillators (e.g., use 200 J biphasic instead of 200 J monophasic). This can be expected to increase the success rate yet decrease the peak current of the first and subsequent shocks.
- To maintain shock efficacy equivalent to that previously observed with monophasic shocks, select a biphasic energy level of about one-third the energy previously used for monophasic shocks (e.g., use 100 J biphasic instead of 300 J monophasic).
- To optimize for low initial and cumulative energy using a step-up protocol, select 70 J for the first shock and use small increases in energy if further shocks are needed.

Each of these strategies should provide effective cardioversion therapy while substantially reducing the amount of peak current to which the heart is exposed.

For cardioversion of atrial arrhythmias other than atrial fibrillation, the data available to guide the selection of energy settings is very limited. It is likely that biphasic doses below 50 J will provide high success rates when treating atrial flutter and paroxysmal supraventricular tachycardia. However, until more clinical data becomes available, it may be advisable to use the same energy settings for biphasic shocks as are customarily used for monophasic shocks.

Arrhythmias may persist for a variety of reasons unrelated to the type of waveform used for cardioversion. In persistent cases, clinicians continue to have the option to either increase shock intensity or switch to an alternate electrode placement.

P. Dorian et al., "External cardioversion of atrial fibrillation with biphasic shocks requires less current and causes less patient discomfort," *Academic Emergency Medicine*, 2001, 8(5):543-44. Abstract.

P. Dorian et al., "A Prospective, Randomized Comparison of Monophasic and Biphasic Shocks for External Cardioversion of Atrial Fibrillation: Shock Efficacy and Post-Procedure Pain," *European Heart Journal*, 2001, 22(supplement):132. Abstract.

R.W. Koster, R. Adams, and F.W. Chapman, "Biphasic truncated exponential shocks provide a high rate of success for external cardioversion of atrial fibrillation," *Resuscitation*, 2000, 45:S52. Abstract.

J. Reisinger et al., "Efficacy of biphasic shocks for transthoracic cardioversion of atrial tachyarrhythmias," *European Heart Journal*, 2001, 22(supplement):132. Abstract.

INTRA-OPERATIVE VENTRICULAR DEFIBRILLATION

Overview

The defibrillation efficacy of Medtronic's biphasic truncated exponential (BTE) waveform was compared to the standard monophasic damped sine waveform (MDS) in a prospective, randomized multi-center study of patients undergoing intra-operative, direct defibrillation for ventricular fibrillation (VF). A total of 251 adult patients were enrolled in the study; 98 of these developed VF that was treated with one or more study shocks. Seven patients who did not satisfy all protocol criteria were excluded from analysis.

Subjects were randomized to receive BTE or MDS shocks from LIFEPAK 12 defibrillator/monitor. Those who developed VF after removal of the aortic clamp received progressively stronger shocks of 2, 5, 7, 10 and 20 joules (J) using 2-inch paddles until defibrillation occurred. A 20 J crossover shock of the alternate waveform was given if VF persisted.

This study showed that these biphasic shocks have higher defibrillation efficacy, requiring fewer shocks, less threshold energy and less cumulative energy than monophasic damped sine shocks.

Objectives

The primary objective of the study was to compare the cumulative efficacy of BTE shocks to MDS shocks at 5 J or less. A triangular sequential design was used to test for a difference between waveform groups.

The secondary objective was to provide an estimation of the dose response relationship for the two waveforms that would allow physicians to make well-informed selections of energy doses for intra-operative defibrillation with biphasic shocks.

Results

Thirty-five male and 15 female subjects were randomized to the BTE group; 34 and 7 to the MDS group. Mean age was 66 and 68 years, respectively. There were no significant differences between BTE and MDS treatment groups for cardiac etiology, arrhythmia history, current cardiac medications, American Society of Anesthesiology (ASA) risk class, left ventricular wall thickness, cardiopulmonary bypass time, core temperature or blood chemistry values at the time of aortic clamp removal.

Cumulative defibrillation success at 5 J or less, the primary endpoint of the study, was significantly higher in the BTE group than in the MDS group (p=0.011). Two of the 91 patients included in this primary endpoint analysis could not be included in more comprehensive analyses due to protocol variances that occurred in the shock sequence after the 5 J shock. Thus, the cumulative success rates for intra-operative defibrillation in the remaining 89 patients are presented in Table B-3 and Figure B-2. These data provide a reasonable estimate of the expected probability of defibrillation success for a single shock at any given energy level within the range studied.

Compared to the MDS group, the BTE group required, on average, fewer shocks (2.5 vs. 3.5: p=0.002), less threshold energy (6.8 J vs. 11.0 J: p=0.003) and less cumulative energy (12.6 J vs. 23.4 J: p=0.002). There was no significant difference between success rates for BTE versus MDS crossover shocks.

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Table B-3 Cumulative Shock Success Rates and Crossover Shock Results for Intra-operative Defibrillation

Energy Setting	2 J	5 J	7 J	10 J	20 J	20 J Crossover Successes
MDS: n = 41	7%	22%	34%	51%	76%	3 of 8 pts succeeded with 20 J BTE shock
BTE: n = 48*	17%	52%	67%	75%	83%	3 of 8 pts succeeded with 20 J MDS shock

*Two subjects randomized to the BTE group were unable to be included in the cumulative success rates shown in the table and figure due to protocol deviations occurring after the 5 J shock.

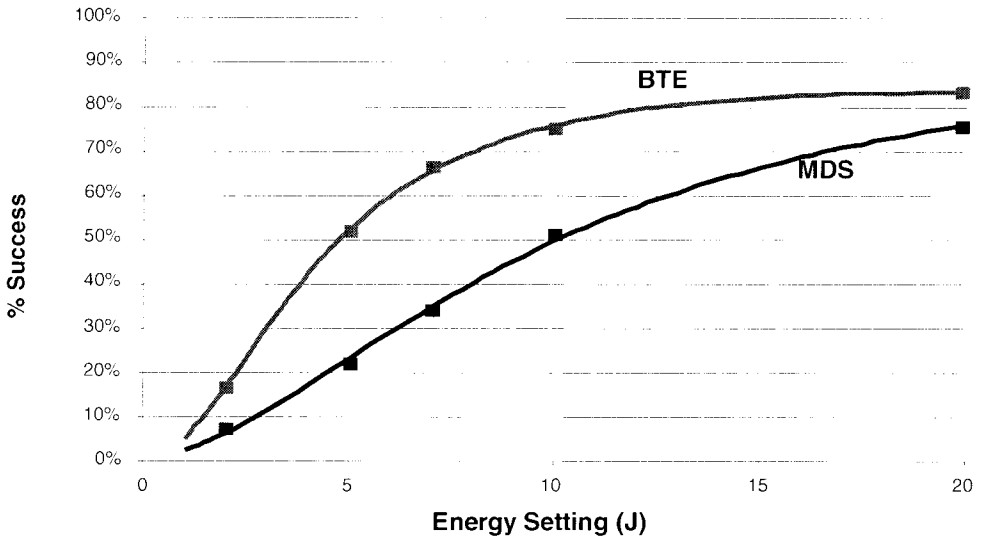

Figure B-2 Cumulative Shock Success for Intra-operative Defibrillation with Monophasic (MDS) and Biphasic (BTE) Shocks: Observed Rates (■) Plotted with Estimated Dose Response Curves

Conclusions

The data demonstrate Medtronic's biphasic waveform is clinically superior to the conventional monophasic damped sine waveform for intra-operative internal defibrillation of VF. Specifically, these biphasic shocks have higher defibrillation efficacy, while requiring fewer shocks, less threshold energy and less cumulative energy than monophasic damped sine shocks. There were no unsafe outcomes or adverse effects from the use of the biphasic waveform.

Guidance for Selection of Shock Energy

Biphasic waveform technology is an emerging standard in cardiac defibrillators. Defibrillation efficacy and dose recommendations have not been previously reported for open chest, direct defibrillation. The results of this study[1] provide specific guidance for three possible strategies in developing a dosing regimen.

- To optimize for lower initial and cumulative energy using a step-up protocol, select 5 J for the first shock and use small incremental increases in energy if further shocks are needed. In this study, biphasic shocks of 5 J were successful in approximately half of the patients.
- To optimize for more rapid defibrillation and fewer shocks, select the same BTE energy level used previously with MDS (e.g., 20 J BTE instead of 20 J MDS), which can be expected to increase the success rate yet decrease by approximately 30% the peak current of the first and subsequent shocks.
- To maintain an equivalent degree of efficacy as previously observed with MDS shocks, a BTE energy level one-half of that previously used for MDS shocks (e.g., 10 J BTE instead of 20 J MDS) would be an appropriate choice.

Each of these strategies should provide effective defibrillation therapy while substantially reducing the amount of peak current to which the heart is exposed.

Fibrillation may persist for a variety of reasons unrelated to the type of waveform used for defibrillation. In cases where fibrillation is persistent, physicians continue to have the option to either increase shock intensity or switch to a larger paddle size. Larger paddle size is known to decrease energy requirements for successful defibrillation.[2]

B. Schwarz et al., "Direct defibrillation during cardiothoracic surgery is more effective with biphasic shocks than monophasic damped sine wave shocks," *European Heart Journal*, 2001, 22(supplement):89. Abstract.

Y. Zhang et al., "Open chest defibrillation: biphasic versus monophasic waveform shocks," *J Am Coll Cardiol*, 2001, 37(2 supplement A):320A.

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APPENDIX C
SCREEN MESSAGES

Summary of Screen Messages Table lists and describes screen messages that the LIFEPAK 20 defibrillator/monitor may display during operation.

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Summary of Screen Messages Table

Message	Description
ABNORMAL ENERGY DELIVERY	A discharge occurred when the paddles were shorted together (refer to warning, page 4-12); an open air discharge occurred; or, the patient impedance is out of range. This message may also appear in certain types of internal faults.
ACCESS DENIED	Three consecutive incorrect passcode attempts were entered.
AED MODE	The device is monitoring the patient condition and functioning as a semiautomatic external defibrillator.
ALARMS SILENCED	The alarms are silenced. An alert tone and this message appear periodically to remind you that alarms have been silenced.
ANALYZING NOW–STAND CLEAR	The AED is analyzing the patient ECG rhythm.
C LEAD OFF	The ECG electrode "C" is disconnected.
CHARGING TO XXX J	The front panel or the standard paddles CHARGE button was pressed.
CHECK FOR PULSE	The AED prompt that appears after each standard 3-shock sequence or NO SHOCK ADVISED message.
CHECK PATIENT	A potentially shockable rhythm is detected when the VF/VT alarm is on.
CHECK PRINTER	The printer door is open; there is no paper in the printer; or, there is another printer malfunction.
CONNECT CABLE	In manual mode, the therapy cable was not connected when you pressed CHARGE. In pacing mode, the QUIK-COMBO cable was not connected when you increased current. In AED advisory mode, the QUIK-COMBO cable was not connected when you pressed ANALYZE.
CONNECT ELECTRODES	The defibrillator detects that the therapy electrodes are disconnected.
CONNECT SYNC CABLE TO REMOTE MONITOR	Remote sync is selected and the device is not connected to the remote monitor.
CONNECT TO AC POWER	Remote sync is selected and the device is not connected to ac power.
CURRENT FAULT	The comparison between delivered and selected pacing current is out of tolerance.
DEMAND	The pacemaker is in the demand mode.
DISARMING...	The decision was made to remove the energy charge.
ECG CABLE OFF	The ECG cable was removed during printing.
ECG LEADS OFF	Multiple ECG electrodes were disconnected either when the device was turned on or during monitoring.
ENERGY DELIVERED	Energy transfer was completed.
ENERGY NOT DELIVERED	An open air discharge is detected with standard paddles. Usually this is because the electrodes are not in contact with a patient or test load when the shock is initiated.

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Message	Description
ENERGY SELECT XXX J	The front panel or standard paddles ENERGY SELECT button was pressed.
IF NO PULSE, PUSH ANALYZE	This message appears following a CPR interval (if activated in setup configuration).
IF NO PULSE, START CPR	Initiate CPR if no pulse and continue with CPR until completion tone.
LA LEADS OFF	ECG electrode LA is disconnected.
L LEADS OFF	ECG electrode L is disconnected.
LL LEADS OFF	ECG electrode LL is disconnected.
F LEADS OFF	ECG electrode F is disconnected.
LOW BATTERY: CONNECT TO AC POWER	A low battery condition exists.
LOW IMPEDANCE: RECHARGING	Patient impedance of <15 ohms detected.
MOTION DETECTED!/ STOP MOTION!	The defibrillator detected motion during ECG analysis, thereby inhibiting analysis.
NO SHOCK ADVISED	The defibrillator does not detect a shockable rhythm.
NON-DEMAND	The pacemaker is in nondemand (asynchronous) mode.
PACER FAULT	The pacemaker detects a pacing fault condition due to high pacing rate or loss of interprocessor communication. Pacing function stops.
PACING STOPPED	Pacing stops and this message appears whenever any of the following occur: pacer electrodes off, pacer cable disconnected, or pacer failure due to high pacing rate or high impedance.
PAUSED	The pacing PAUSE button was pressed and held. Current pulses are applied at reduced frequency while the mA and ppm settings are maintained.
PUSH ANALYZE	Press ANALYZE to begin ECG analysis.
PUSH SPEED DIAL TO DISARM	An instruction on the charging screen overlays for disarming the charge.
PUSH PADDLE BUTTON TO SHOCK!	The front panel SHOCK button is disabled if internal paddles are attached. This message appears if you attempt to transfer energy by pressing the front panel SHOCK button.
PUSH PADDLE BUTTONS TO SHOCK!	If standard paddles are attached, the front panel SHOCK button is disabled. Message appears if you attempt to transfer energy by pressing the front panel SHOCK button.
PUSH SHOCK BUTTON!	The defibrillator is fully charged and ready to provide therapy (a therapy cable or internal paddles must be connected).
RA LEADS OFF	ECG electrode RA is disconnected.
R LEADS OFF	ECG electrode R is disconnected.
RL LEADS OFF	ECG electrode RL is disconnected.
N LEADS OFF	ECG electrode N is disconnected.

Message	Description
SEARCHING FOR SIGNAL	Remote sync is selected and the device is qualifying the input signal.
SELF TEST DID NOT COMPLETE	Test plug not connected to QUIK-COMBO therapy cable or standard paddles not seated in paddle wells during daily auto test.
SELF TEST DID NOT COMPLETE - CONNECT TO TEST PLUG	Test plug not connected to QUIK-COMBO therapy cable or standard paddles not seated in paddle wells during daily auto test.
SELF TEST FAILED	An unsuccessful self test has occurred.
SELF TEST IN PROGRESS	Confirms that the self test is in progress.
SELF TEST SUCCEEDED	A successful self test was completed.
SHOCK ADVISED!	The defibrillator detected a shockable rhythm.
SPO2: LOW PERFUSION	Patient has a weak pulse.
SPO2: NO SENSOR DETECTED	A sensor was disconnected from the monitor.
SPO2: SEARCHING FOR PULSE	Confirms the pulse oximetry sensor is connected to the defibrillator.
SPO2: CHECK SENSOR	The SpO2 sensor detached from the patient after a measurement was obtained.
STAND CLEAR/PUSH SHOCK BUTTON	Stand clear of the patient and push the SHOCK button.
SWITCHING PRIMARY TO LEAD II	Paddles lead is not available and you pressed the ADVISORY button.
SWITCHING PRIMARY TO PADDLES	Paddles lead is available and you pressed the ADVISORY or ANALYZE button.
USE ECG LEADS	The device is attempting synchronized cardioversion and paddles lead was selected.
USER TEST DID NOT COMPLETE	Test plug not connected to QUIK-COMBO therapy cable or standard paddles not seated in paddle wells during user test.
USER TEST DID NOT COMPLETE - CONNECT TO TEST PLUG	Test plug not connected to QUIK-COMBO therapy cable or standard paddles not seated in paddle wells during user test.
USER TEST FAILED	An unsuccessful user test has occurred.
USER TEST IN PROGRESS	Confirms that the user test is in progress.
USER TEST SUCCEEDED	A successful user test was completed.

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APPENDIX D
OPERATOR'S CHECKLIST

This Operator's Checklist may be reproduced.

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RATOR'S CHECKLIST

Serial No.: _____

tion: _____

device. Inspection and testing of this device on a daily basis is recommended. You may also consult JAMA, August 22/29, 1990, Vol. 264, No. 8, Table 2 for the Defibrillator Working Group's manual defibrillator checklist.

This form may be reproduced.

Medtronic

Instruction	Recommended Corrective Action	Date							
		Initials							

Insert a ✔ in the box after completing each instruction.

pect physical condition for:

reign substances	Clean the device.							
mage or cracks	Contact qualified service personnel.							

pect Power Source for:

power connector plugged into unit and ac ver source; LED is lit	Contact qualified service personnel.							
ken, loose, or worn power cable	Replace damaged or broken parts.							

eck therapy and ECG electrodes for:

e By date	Replace if past.							
are electrodes available	Obtain spare electrodes.							
amine accessory cables for cracking, nage, broken or bent parts or pins, l paddle surfaces for pitting.	Replace damaged or broken parts.							

connect the device from ac power, ss ON and look for:

F-TEST messages	If absent, contact qualified service personnel.							
mentary illumination of each LED l all LCD segments	If absent, contact qualified service personnel.							
V BATTERY/CONNECT TO AC POWER ssages	Connect to ac power.							
RVICE INDICATOR message	Contact qualified service personnel.							
form user test (QUIK-COMBO therapy le only)	If test failed, repeat. If failed twice, contact qualified service personnel.							
form standard paddles defibrillation ck	If test failed, repeat. If failed twice, contact qualified service personnel.							

eck ECG printer for:

equate paper supply	Replace if necessary.							
lity to print	If not working, contact qualified service personnel.							

APPENDIX E
SHOCK ADVISORY SYSTEM

This appendix describes the basic function of the Shock Advisory System (SAS).

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OVERVIEW OF THE SHOCK ADVISORY SYSTEM

The Shock Advisory System (SAS) is an ECG analysis system built into the LIFEPAK 20 defibrillator/monitor that advises the operator as to whether it detects a shockable or nonshockable rhythm. This system makes it possible for individuals who are not trained to interpret ECG rhythms to provide potentially lifesaving therapy to victims of ventricular fibrillation or pulseless ventricular tachycardia. The Shock Advisory System contains the following features:

- Electrode Contact Determination
- Automated Interpretation of the ECG
- Operator Control of Shock Therapy
- Continuous Patient Surveillance System (CPSS)
- Motion Detection

The Shock Advisory System is active when the LIFEPAK 20 defibrillator/monitor is used as an automated external defibrillator (AED). CPSS may be activated during monitoring.

Electrode Contact Determination

The Shock Advisory System measures the patient's transthoracic impedance through the therapy electrodes. If the baseline impedance is higher than a maximum limit, it determines that the electrodes do not have sufficient contact with the patient or are not properly connected to the AED. When this occurs, ECG analysis and shock delivery are inhibited. The AED advises the operator to connect electrodes when there is insufficient electrode contact.

Automated Interpretation of the ECG

The Shock Advisory System recommends a shock if it detects the following:

- Ventricular fibrillation - with a peak-to-peak amplitude of at least 0.08 mV.
- Ventricular tachycardia - defined as having a heart rate of at least 120 beats per minute, QRS width of at least 0.16 seconds, and no apparent P waves.

Pacemaker pulses may prevent advisement of an appropriate shock, regardless of the patient's underlying rhythm. The Shock Advisory System recommends no shock for all other ECG rhythms including asystole, pulseless electrical activity, idioventricular rhythms, bradycardia, supraventricular tachycardias, atrial fibrillation and flutter, heart block, premature ventricular complexes and normal sinus rhythm. These rhythms are specifically mentioned in the AHA recommendations.

SAS performance is summarized in the following tables E1 and E2.

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Table E-1 LIFEPAK 20 Series SAS Performance

Rhythm Class	ECG Test[1] Sample Size	Performance Goal	Observed Performance
Shockable: Coarse VF	168	>90% sensitivity	LIFEPAK 20 series meets the AAMI DF39[2] requirements and AHA recommendations[3].
Shockable: VT	65	>75% sensitivity	LIFEPAK 20 series meets the AAMI DF39 requirements and AHA recommendations.
Nonshockable: NSR	144	>99% specificity for NSR (AHA)	LIFEPAK 20 series meets the AHA recommendations.
Nonshockable: asystole	43	>95% specificity	LIFEPAK 20 series meets the AAMI DF39 requirements and AHA recommendations.
Nonshockable: all other rhythms	531	>95% specificity	LIFEPAK 20 series meets the AAMI DF39 requirements and AHA recommendations.
Intermediate: fine VF	29	Report only	92.1% sensitivity

From Medtronic ECG database. Each sample is run 10 times asynchronously.
Association for the Advancement of Medical Instrumentation. DF39-1993 Standard for Automatic External Defibrillators and Remote-Control Defibrillators. Arlington, VA: AAMI;1993.
Automatic External Defibrillators for Public Access Defibrillation: Recommendations for Specifying and Reporting Arrhythmia Analysis Algorithm Performance, Incorporating New Waveforms, and Enhancing Safety. AHA Task Force on Automatic External Defibrillation, Subcommittee on AED Safety and Efficacy. *Circulation.* 1997; Vol. 95: 1677-1682.
VF = ventricular fibrillation
VT = ventricular tachycardia
NSR = normal sinus rhythm

Operator Control of Shock Therapy

The Shock Advisory System causes the AED to charge automatically when it detects the presence of a shockable rhythm. When a shock is advised, the operator presses the SHOCK button to deliver the energy to the patient.

Continuous Patient Surveillance System

The Continuous Patient Surveillance System (CPSS) automatically monitors the patient's ECG rhythm for a potentially shockable rhythm while the electrodes are attached and the AED is turned on. CPSS is not active during ECG analysis or when the AED is in a CPR cycle.

Motion Detection

The Shock Advisory System detects patient motion independent of ECG analysis. A motion detector is designed into the LIFEPAK 20 defibrillator/monitor.

A number of activities can create motion, including CPR, rescuer movement, patient movement, or vehicle movement. If variations in the transthoracic impedance signal exceed a maximum limit, the Shock Advisory System determines that patient motion of some kind is present. ECG analysis is inhibited until the motion ceases. The operator is advised any time motion is detected during an analysis by a displayed message, a voice prompt, and an audible alert. If the motion does not cease within 20 seconds, analysis attempts will stop until the operator presses the ANALYZE button again. If the motion ceases within 20 seconds, ECG analysis proceeds automatically.

There are two reasons why ECG analysis is inhibited when motion is detected:

1. Such motion may cause artifact in the ECG signal. This artifact can cause a nonshockable ECG rhythm to look like a shockable rhythm. For example, chest compressions during asystole can look like shockable ventricular tachycardia. Artifact can also cause a shockable ECG rhythm to look like a nonshockable rhythm. For example, chest compressions during ventricular fibrillation can look like an organized and, therefore, nonshockable rhythm.
2. The motion may be caused by a rescuer's interventions. To reduce the risk of inadvertently shocking a rescuer, the motion alert prompts the rescuer to move away from the patient. This will stop the motion and ECG analysis will proceed.

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APPENDIX F
DOCKING STATION

This appendix describes how to install and use the LIFEPAK 20 defibrillator/monitor docking station.

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LIFEPAK 20 DEFIBRILLATOR/MONITOR DOCKING STATION (PN 3201551)

The LIFEPAK 20 defibrillator/monitor docking station allows you to secure your defibrillator to an emergency cart or other flat surface. The docking station provides a 360-degree turning radius for the viewing of the LIFEPAK 20 defibrillator/monitor display from any angle.

To insert the LIFEPAK 20 defibrillator/monitor into the docking station:

1. Hold the LIFEPAK 20 defibrillator/monitor by the handle over the docking station (see Figure F, arrow 1).
2. Tilt the LIFEPAK 20 defibrillator/monitor backward into the docking station, aligning slots in the rear of the device to rollers on the docking (see Figure F, arrow 2).
3. Align recess in lower front panel of the LIFEPAK 20 defibrillator/monitor with the front roller on the docking station and press down on the front of the LIFEPAK 20 defibrillator/monitor until you hear a click (see Figure F, arrow 3.
4. Check to make sure that the LIFEPAK 20 defibrillator/monitor is securely locked into position.

To turn the LIFEPAK 20 defibrillator/monitor while in the docking station:

1. Grasp the LIFEPAK 20 defibrillator/monitor by the handle, or by its sides.
2. Turn to the correct position. You will hear clicking sounds as the device locks into place.

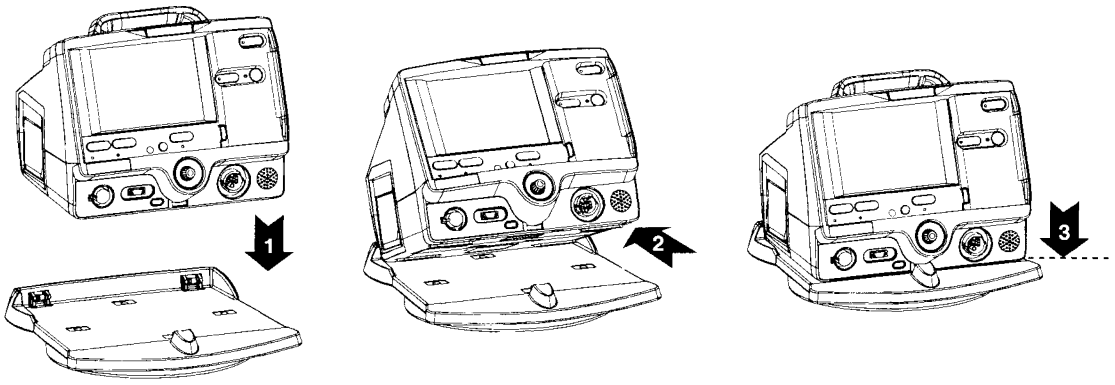

Figure F Docking Station

To remove the LIFEPAK 20 defibrillator/monitor from the docking station:

1. Grasp the LIFEPAK 20 defibrillator/monitor by the handle.
2. Pull briskly on the LIFEPAK 20 defibrillator/monitor until it releases from the docking station.

Note: To install the docking station to a flat surface or wall mount (GCX) bracket, refer to the docking station installation instructions or consult the LIFEPAK 20 Defibrillator/Monitor Service Manual.

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APPENDIX G
DECLARATION OF CONFORMITY

2002–2004 Medtronic Physio-Control Corp.

CE 0123

DECLARATION OF CONFORMITY
according to EN 45014

Medtronic PHYSIO-CONTROL

Manufacturer's Name: **Medtronic Physio-Control Corp.**

Manufacturer's Address: **11811 Willows Road NE**
P.O. Box 97006
Redmond, WA 98073-9706 USA

declares that the CE-marked product

Product Name: LIFEPAK 20 defibrillator/monitor

Part Number(s): 3200500

complies with 93/42/EEC (Medical Device Directive) class IIb. Conformity assessed per Annex II.
This product complies with:

Safety:	EN60601-1:1996/IEC 60601-1:1995 CLASS I, type BF with CF parts/Continuous operation IEC 60601-2-4:1983 EN 60601-2-25/IEC 60601-2-25:1993 UL 2601-1:10-24-97*	
EMC:	EN60601-1-2:1993	
	EN 55011:1991	Class B, Group 1
	EN 61000-4-2/IEC 61000-4-2:1995	3kV CD, 8kV AD
	EN 61000-4-3:1996/IEC 61000-4-3:1995	3 V/m
	EN 61000-4-4/IEC 1000-4-4:1995	0.5 kV Power Lines
	EN 61000-4-5/IEC 1000-4-5:1995	0.5 kV Power Lines and per EN 60601-1-2

*Tested according to Figure 11 of UL 2601-1:10-24-97

Supplementary Information
Included are the following accessories and interconnecting cables:

- QUIK-COMBO™ pacing/ defibrillation/ECG electrodes
- QUIK-COMBO PEDIATRIC pacing/defibrillation/ECG electrodes
- QUIK-COMBO RTS pacing/ defibrillation/ECG electrodes
- QUIK-COMBO REDI-PAK™ pacing/defibrillation/ECG electrodes
- FAST-PATCH® pacing/ defibrillation/ECG electrodes
- FAST-PATCH PLUS pacing/ defibrillation/ECG electrodes
- Standard paddles with built in pediatric paddles (two required)
- External sterilizable paddles
- Posterior paddles
- Internal handles with discharge controls
- Serial cable (system connector)
- FAST-PATCH defibrillation cable
- 3-lead ECG cable, 5-lead cable
- QUIK-COMBO defibrillation cable
- SpO2 cable PC04 (4 feet), PC08 (8 feet), PC12 (12 feet)
- SpO2 sensor, hard shell, finger (adult and pediatric)
- SpO2 Disposable sensors (Masimo compatible) (adult and pediatric)
- SpO2 Option
- External Pacing Option
- Docking Station
- QUIK-COMBO Test Plug

Redmond, August 5, 2002

Michael D. Willingham
Vice President of Quality and Regulatory Affairs

European Contact: Your local Medtronic Sales and Service Office or
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SA Device Tracking

ɜ U.S. Food and Drug Administration classifies defibrillators as a medical device that requires tracking (knowing ɜre the device is). As such, federal regulations require that manufacturers maintain tracking information for each ice distributed. We rely on our customers to provide accurate device location information. This tracking rmation provides the manufacturer the ability to locate the device and perform a product correction, should it ever ɲeeded.

ɔking information must specify the physical location of the device, not just the headquarters or receiving ıartment's shipping address. The tracking information required is:

ustomer name and department name

ctual physical location (for example, 123 Main Street, Third Floor, Suite A, City, State, Zip Code)

contact name and telephone number

evice part number and serial number

address to which this particular device was shipped is the current tracking location. If this device is located ıewhere other than the shipping address, or you have purchased this device from someone other than Medtronic sio-Control, please either call the device tracking coordinator at 1.800.426.4448, or use one of the postage-paid ress change cards below to update this vital information.

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